PHARMACEUTICAL PRICE CONTROLS AND OTHER MARKET ACCESS BARRIERS IN DEVELOPED COUNTRIES

PhRMA

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I. ABOUT THIS REPORT

PhRMA and its member companies are pleased to provide this preliminary report on foreign price controls and other market access barriers in the OECD countries. This purpose of this report is to assist the U.S. Government in responding to the study mandated in the Medicare Modernization Act, enacted in December 2003, requiring, *inter alia*, a description of the mechanisms used by foreign governments to distort competition in the pharmaceutical marketplace with price controls and other market access barriers. The purpose of these country summaries is to provide a convenient high-level snapshot of the pharmaceutical pricing and reimbursement scheme in each market. These systems are highly complex and vary considerably around the world. The attached report is not intended to catalogue all of the market access and other trade barriers faced by the U.S. pharmaceutical industry in each market. Rather, it is meant only as an introductory reference tool, providing purely descriptive information on the bureaucratic schemes that distort international trade in pharmaceuticals and depress innovation.

Each Country Summary has four parts. The first section is entitled "Health Care Financing" and provides a short description of the national health insurance systems in each of these markets. The second section is entitled "Pharmaceutical Market" and contains summary statistics on the size of the total pharmaceutical health care and generics market (where available). For each country, the figures used were based on one of the following sources: (1) data cited in publications entitled "Pharmaceutical Pricing and Reimbursement 2003"[1] and "Pharmaceutical Pricing and Reimbursement in European Accession Countries 2004,"[2] most of which is sourced from OECD Health Database or IMS Knowledge Link; (2) PhRMA Annual Survey data (available for some countries); or (3) where that data was more recent, figures from the local pharmaceutical company organizations in the relevant country.

The third section of each Country Summary is entitled "Pricing, Reimbursement and Access," and provides a descriptive overview of the pricing and reimbursement regulatory regime in each country. In some countries, these are wholly separate processes, requiring sequential and extensive industry submissions to two or more regulatory authorities – one in charge of determining whether a product can be made available through the national health system at all (the reimbursement authority), and another in charge of determining the price at which it will be reimbursed (the pricing authority). Further complicating the picture, in some countries, regional or local officials have at least partial

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[1] PPR Communication Ltd., Pharmaceutical Pricing & Reimbursement 2003: A Concise Guide (2003), available at www.imshealth.com.

[2] PPR Communication Ltd., Pharmaceutical Pricing & Reimbursement in European Union Accession Countries 2004: A Concise Guide (2004), available at www.imshealth.com.

responsibility for these decisions and processes. In the vast majority of the countries included in this report, these government reimbursement processes represent virtually the entire market in the country. The small size of the private market, where one is available at all, makes pharmaceutical company engagement in the government pricing and reimbursement scheme of crucial importance, and further highlights in the importance of reforms to those systems.

In addition, this section includes some additional information on other important cost-containment mechanisms used by foreign governments to target pharmaceuticals. These mechanisms include, for example, "rebate" or "clawback" provisions, pursuant to which pharmaceutical manufacturers themselves literally have to pay large sums to the government if they sell more medicines in a given year than had been predicted by government budget-makers.

Finally, this section of the Country Summaries also provides some information on the trade problems encountered by the industry in attempting to access the markets subject to these bureaucratic regimes, but this information is by no means comprehensive. For example, one major trade problem in the vast majority of OECD countries that is not discussed extensively is barriers to providing information to patients. A tool used by most foreign governments to artificially suppress demand for innovative medicines is simply to ensure that their patients do not know what they are missing. In virtually every OECD country, pharmaceutical manufacturers are barred from communicating directly with the people most affected by their products: patients. This ban not only applies to communications media like TV and radio, but also to the Internet. (Many of those governments are now even going a step further and severely restricting the ability of pharmaceutical manufacturers to provide information to doctors about their products.) Precisely because these restrictions on providing information to patients are so wide-spread and do not vary greatly among the countries included in this report, the report does not go into detail about the regulatory nuances in each country.

The fourth and final section of each Country Summary is entitled "Research and Development", and contains statistics (where available) on the level of pharmaceutical research and development in each country.

PhRMA welcomes questions and comments on this report. We seek to inform the public debate on the benefits for patients everywhere from liberalizing the health care market abroad. Foreign price controls and other market access barriers have for years depressed innovation and shifted an unfair portion of the cost of developing new medicines to U.S. consumers. We fully support a strong U.S. Government initiative to advocate for market-oriented reforms to address this situation in our major trading partners.

II. COUNTRY SUMMARIES

AUSTRALIA

Health Care Financing:

A largely government funded national system of health care, "Medicare," provides universal access to all public hospital services and a comprehensive range of other medical services, including primary health care, vaccinations and prescription pharmaceuticals in Australia. Limited private insurance is available and covers a range of in-hospital and ancillary medical services, such as physiotherapy and dental services.

Pharmaceutical Market:

In 2001, the domestic pharmaceutical market in Australia was estimated at US$ 3,101 million.[3] Sales of ethical pharmaceuticals by PhRMA member companies in 2002 totaled US$ 1555.8 million in Australia and New Zealand, comprising 0.8% of total global sales.[4] Total health spending per capita totaled US$ 1,758 in 2000, and total healthcare expenditure as a percentage of GDP was 8.3%.[5]

Pricing, Reimbursement and Access:

Australian prescription drug prices are the second lowest in the OECD. Prescription drugs and medicines are available through two main outlets: independent private sector pharmacies and public hospitals. Independent private sector pharmacies provide pharmaceuticals that are subsidized by the federal-level Pharmaceutical Benefits Scheme (PBS). The state governments pay for all hospital in-patient pharmaceuticals using grants from the federal government. The PBS subsidizes approximately 96% of all prescription drugs at private pharmacies.

For out-patient pharmaceuticals, Australia operates a positive list system in which reimbursement is limited to those medicines that have been formally admitted to the PBS list, and for which a reimbursement price has been determined by the Government. The PBS process involves a detailed review of scientific, economic and comparative data related to a new medicine, and requires the submission of an extensive dossier on these issues. The PBS process generally begins after the Therapeutic Goods Administration (the equivalent of the U.S. FDA) approves a medicine as being safe and effective.

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[3] PPR Communication Ltd., Pharmaceutical Pricing & Reimbursement 2003: A Concise Guide (Australia), 2 [hereinafter Pharmaceutical Pricing & Reimbursement 2003 (country chapter)].

[4] PhRMA Profile 2004: Focus on Innovation, 46, available at www.phrma.org.

[5] Pharmaceutical Pricing & Reimbursement (Australia), 1.

After receiving such regulatory approval to access the Australian market, the sponsoring company must apply to the Pharmaceutical Benefits Advisory Committee (PBAC) for listing the drug on the PBS reimbursement list. The PBAC will then refer the application to its Economics Sub-committee, and will ultimately issue a recommendation regarding the listing of the drug based largely on its supposed comparative cost-effectiveness. If the PBAC issues a positive recommendation, the dossier for the drug is then sent to the Pharmaceutical Benefits Pricing Authority (PBPA) which recommends a price. The final decision regarding PBS listing and pricing rests with the Ministry of Health.

The PBAC and PBPA rely heavily on a reference pricing system in determining the cost-effectiveness and price of a new medicine. Many drugs are classified in "therapeutic groups". Under Therapeutic Group Pricing, the prices of all drugs in the group are linked together, and benchmarked to the lowest-priced drug within the group. Australia's use of stringent reference pricing was a key U.S. concern during the recent negotiation of the U.S. – Australia Free Trade Agreement (FTA).

Another major problem with the PBS concerns restricted listings. Increasingly, the PBS approves drugs for inclusion on its reimbursement list for only a narrow range of indications. In practice, these restrictive listings deny Australian patients access to medicines that Australia's own health authorities have approved as safe and effective for the treatment of a range of conditions.

The entire PBS system is significantly lacking in transparency. These transparency problems have been recognized and criticized in several of the Australian governments own reports on the system. The system has also been plagued by long bureaucratic delays. PhRMA members report that it is very common for companies to experience multi-year delays in PBS reviews of new drugs. For these reasons, the pharmaceutical industry applauds the conclusion of the U.S.-Australia Free Trade Agreement, which includes new obligations requiring Australia to improve the transparency and functioning of the PBS process.

Unfortunately the U.S. – Australia FTA did not require Australia to address the distortions and disparities caused by its reference pricing system and other pricing procedures. The Agreement establishes a Medicines Working Group that will work on addressing some of these continuing issues, and PhRMA members look forward to working with the U.S. Government to make progress in that forum.

Research and Development:

In 2002, R&D of ethical pharmaceuticals by PhRMA Member Companies in Australia and New Zealand totaled US$ 80 million.[6]

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[6] PhRMA Profile 2004: Focus on Innovation, at 42.

AUSTRIA

Health Care Financing:

Austria has a national social security system that provides healthcare, pensions and accident insurance. Delivery of services occurs through 14 sickfunds. A combination of social insurance, general taxation, employer contributions and private co-payments finances the sickfund schemes.

Pharmaceutical Market:

In 2002, the Austrian pharmaceutical market was valued at € 1,885 million. In 2000, total healthcare spending totaled US$ 15.7 billion, healthcare expenditure per capita was US $1,933, and healthcare spending as a percentage of GDP totaled 8.0%.[7] In 2001, generic drugs accounted for 4.5% of purchased medicines by value.

Pricing, Reimbursement and Access:

The Hauptverband or the Association of Austrian Social Security Institutions, oversees all Austrian sickfund schemes and is the decision-making body for pharmaceutical reimbursement. The Hauptverband uses three types of evaluation to determine reimbursement: pharmacological, medical-therapeutic, and economic. Pharmacological evaluation determines whether a new product is therapeutically different than other products already listed. Medical-Therapeutic evaluation determines whether the new product provides an improved health outcome for patients in comparison to products already listed. Finally, the economic evaluation determines whether the product is cost-effective in comparison to older, listed products.

Pharmaceuticals meeting the evaluation criteria set by the Haupterverband are included on a Positive List. Pharmaceuticals that are not on the positive list can be reimbursed only after gaining "prior approval from the Chief Medical Officer of the sickfund."[8] In practice, only reimbursed pharmaceuticals are regularly prescribed by doctors in Austria.

The Ministry of Health is responsible for determining pricing of innovative and generic pharmaceuticals in Austria. Innovative pharmaceutical prices are based on a reference pricing scheme that uses the average European price as the maximum price for a product. Launch prices of generic pharmaceuticals are set at 30% below the price of the innovative product. Once a generic version enters the market, the original product's price is then reduced to a maximum of 10% more than the generic price. In short, the entry of generic products leads to a market price digression for the innovative product. A reform package that went

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[7] Pharmaceutical Pricing and Reimbursement 2003 (Austria), at 14.

[8] *Id.*

into effect in January 2004 will lead to a more aggressive price reduction for generics in the future. By 2006, generic products will be priced at 52% of the original product's price. To stay reimbursed, the original product will have to match that price level.

Patient co-payments are flat at € 4.35 per unit (US $5.19) except for economically vulnerable persons who are exempt from co-payments (about 12% of all insured persons). Private insurance and out of pocket payments are relevant in the comparably small OTC market only.

PhRMA members' experience with the Austrian reimbursement system is that it is highly bureaucratic and non-transparent, and has a systematic bias against innovation. Major issues within the Austrian market include access delays for patients to innovative medicines, and ex-factory prices for innovative medicines that are significantly below the EU average (between 16% and 30%).

Research and Development

Data on pharmaceutical R&D expenditures in Austria in 2002 is not available.

BELGIUM

Health Care Financing:

Compulsory healthcare insurance is available to all Belgian citizens through the National Institute for Sickness and Invalidity (Institut National d'Assurance Maladie et d'Invalidité, INAMI). Financing of the system occurs through a combination of employer and employee contributions, national taxation, patient co-payments, and private insurance. Private insurance is available for purchase to cover services not provided by the national health insurance scheme.[9]

Pharmaceutical Market:

In 2002, the Belgium pharmaceutical market was valued at US$ 3.9 billion and represented approximately 22 % of the total healthcare bill. Total healthcare expenditures as a percentage of GDP totaled 5.4%. Per capita, total healthcare expenditures amounted to US$ 1,744 and pharmaceutical expenditures totaled US$ 378. Government reimbursement presumptions account for 85% of the generics market, pharmacists' margin, and pharmaceutical market in Belgium.

Pricing, Reimbursement, Access:

The Pricing Commission (Commission des Prix des Spécialités Pharmaceutiques) in the Ministry of Economic Affairs determines pharmaceutical pricing in Belgium. The Pricing Commission sets a maximum price for which a drug can be sold in Belgium. Such price is based on an evaluation of the price for the drug in other European countries, the price for similar products already on the market, research and development costs, administrative costs, and salary. "There is a tendency for Belgian prices to be based on the lowest European levels."[10] In theory, manufacturers may apply with the Pricing Commission for a price increase; however, the Government of Belgium has had a long-standing price freeze in place for reimbursed medicinal products and has implemented repeated price decreases in the past 10 years.[11]

Reimbursement decisions are made by the Medicines Reimbursement Commission (Commission de Remboursement des Médicaments, CRM) based in the National Institute for Sickness and Invalidity. The CRM bases its decision on whether or not to include a drug on its reimbursement list from the following criteria: price and proposed reimbursement level, value of the product to improving a patient's health outcome in comparison to similar products on the market, and health insurance cost implications. A reference price system that applies to a large number of pharmaceutical products was introduced in 2002. Under this system, innovative products are reimbursed at a rate of 26% less than

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[9] Pharmaceutical Pricing and Reimbursement (Belgium), at 21.

[10] *Id.*

[11] *Id.*

the original price approved by the Pricing Commission.[12] There are six rates of reimbursement based on the severity of illness. The most severe illnesses have a reimbursement rate of 100%; less severe illnesses have reimbursement rates set at 0, 20, 40, 50, or 75 per cent.[13]

Delays in approving reimbursement in Belgium have shortened from a staggering 600+ days to around 230 days as a result of a new medicine law. This review process is still too time consuming from the patient perspective and should be shortened to be in full compliance with the EU Transparency Directive mandate of 180 days.

In sum, Belgium has one of the more restrictive environments for pharmaceutical sales in Europe. The government relies on annual taxes on companies and price cuts to align government budgetary outlays with patient demand. To date, the government has refused to ask patients to bear a greater burden of the costs of their healthcare through a system of co-payments.

Research and Development:

R&D figures from PhRMA member companies in Belgium are not available.

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[12] *Id.*, at 22-23.
[13] *Id.*

CANADA

Health Care Financing:

Universal, public health care covering physician and hospital services is available to all Canadian residents. Health care is administered provincially, and is financed through federal transfer payments to the provinces and provincial taxation. During the past ten years, however, significant cost shifting has taken place. Canadian provinces have expanded coverage for drugs and other services to specific populations without federal government matching funding transfers. Each of the provincial health insurance schemes in Canada operates somewhat differently, based on differences in local culture and the relative sizes of the population and economy.

Pharmaceutical Market:

In 2001 the Canadian pharmaceutical market was valued at US$ 6,930 million.[14] Healthcare spending per capita totaled US$ 2,134 million. Total healthcare expenditure as a percentage of GDP totaled 9.1%.[15]

Pricing, Reimbursement and Access:

Both the federal and provincial governments regulate prescription drug prices in Canada. At the federal level, the Patented Medicine Prices Review Board (PMPRB) is charged with reviewing the suggested prices (both at launch and subsequently) of patented medicines to determine that they are "non-excessive."

The PMPRB determines whether the price suggested by a manufacturer is "non-excessive" by placing the drug in one of three categories. The price of "breakthrough products" cannot be higher than the median price of the drug in the US, France, Germany, UK, Italy, Switzerland, and Sweden. The price of a line extension product must be in the range of the cost of therapy for existing drugs used to treat the same disease. Other products, deemed of "minor improvement," can have a price equal to, but no higher than, the highest price of the class in Canada at the time the product comes to market. In addition, products are not permitted to have price increases of greater than the Consumer Price Index. If company prices a drug higher than the price determined by the PMPRB, it may be asked to lower its price until the excess has been paid off (*e.g.*, provide lower prices to payors to cover the differential), or reimburse the excess to the government. The company may also be fined.

Recently, the PMPRB has been working toward revising its overall approach to setting price ceilings. Reports emerging from the Federal/ Provincial/Territorial Pharmaceutical Issues Committee suggest the likelihood of increased

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[14] Pharmaceutical Pricing and Reimbursement 2003 (Canada), at 27.
[15] *Id.*

collaboration among different levels of government toward more stringent, non-market based interventions in the future.

The PMPRB, however, represents only the first level of price control in Canada. Once the price of a drug has been deemed "non-excessive" by the PMPRB, individual provinces decide whether it will be placed on the provincial formulary for reimbursement, and at what price. The review process in some provinces regularly exceeds one year, during which time Canadian patients are denied access to the drug at issue.

Each Canadian province has its own rules for determining what drugs will be covered under the provincial health plan, and the reimbursement price for those drugs. There is substantial variability among the provinces in the decisions to list new drugs and the time taken to review submissions for adding drugs to provincial formularies. In the five-year period ending August 2003, of 288 new medicines introduced to the Canadian market, the percentage of these approved for listing (either with or without restrictions) on individual provincial formularies ranged from a high of 55% in one province to a low of 21% in another. Access to effective treatments for a disease, therefore, varies greatly by location within Canada.

Only the province of British Columbia has an official system of Reference Pricing. The provinces of Ontario and Quebec, however, have *de facto* imposed a price freeze for the past 10 years, thus preventing companies from availing themselves of their legitimate CPI increases. The reimbursement policies and prices adopted by these provinces are particularly important, and onerous, because they are the most populous provinces and because private insurers widely follow their lead.[16] These policies not only hurt pharmaceutical manufacturers, but Canadian patients as well. In British Colombia, where the reference pricing system results in year-to-year changes in the provincial formulary, in a 1997 survey physicians reported that 90 percent of their patients were forced to change medications simply as a result of reference pricing. The reported health implications of these shifts include adverse effects, worsened symptoms, and hospitalizations.[17]

In recent years, there has been an initiative in Canada to increase collaboration among the provinces on pharmaceutical benefits plan management. A new process, known as the Common Drug Review Process, went into effect in September 2003. The CDR is a single process for undertaking reviews of cost—effectiveness and providing listing recommendations for new drugs to participating drug benefit plans in Canada. Even under the CDR, however, each provincial jurisdiction in Canada will continue to make its own decision regarding whether to list a product. There is great concern that the CDR process will thus

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[16] Pharmaceutical Pricing and Reimbursement 2003 (Canada), at 31.

[17] Canadian Association of Retired Persons, "CARP Survey: BC's New Drug Plan Hurts," Fifty Plus Net – CARP in Action, May 14, 1997.

serve only to further lengthen the process of regulatory review in Canada, and could result in "lowest common denominator" type results for listing across the country.

Notably, price regulation in Canada is purely at the manufacturer level, not the retail level. The average pharmacy mark up in Canada is very high -- 52% of the manufacturers' selling price.[18]

Research and Development:

In 2001, pharmaceutical sector R&D spending in Canada totaled US$ 304.5 million. This figure reflects a decline in pharmaceutical sector R&D spending by almost 50% from 1998 where R&D spending totaled approximately US$ 595.0 million.[19]

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[18] Pharmaceutical Pricing and Reimbursement 2003 (Canada), at 34.

[19] PhRMA Profile 2004: Focus on Innovation, 42. International Trade Commission, "Pricing of Prescription Drugs" Investigation No. 332-419 (Washington D.C.: International Trade Commission, December 2000) [hereinafter ITC Pricing Report].

CZECH REPUBLIC

Health Care Financing:

Healthcare is provided on the basis of mandatory public health insurance, established by law. Residents are not allowed to "opt-out" of the system, although approximately 10% of the population takes out supplementary insurance.[20] Health care is financed through contributions from individuals, employers and the state.[21]

Pharmaceutical Market:

In 2002, the pharmaceutical market in the Czech Republic totaled US$ 1 billion.[22] Healthcare spending per capita totaled US$ 358. Total healthcare expenditure as a percentage of GDP equaled 7.2%.[23]

Pricing, Reimbursement and Access:

All pharmaceutical products registered for commercial purposes in the Czech Republic are subject to government price regulation. The Ministry of Finance sets the maximum legal ex-factory price for all drugs regardless of their reimbursement status. Different criteria are applied for maximum pricing for domestic products versus imported R&D products.[24] The Ministry of Finance reviews prices once per year. Companies have an opportunity to request changes in price, but the Ministry rarely grants requests for price increases.[25]

For reimbursement purposes, pharmaceuticals are classified into three reimbursement lists, including a separate generic list. Generally, generic drugs are reimbursed fully by the government, while others require a co-payment. The level of patient co-payments is lower than any other European county except for the Netherlands.

A government committee, named the "Categorization Committee," makes reimbursement decisions in the Czech Republic. The Committee is comprised of representatives of the Ministry of Health, as well as representatives of the medical and pharmaceutical sectors, insurance funds and patient groups. It meets twice a year to decide which pharmaceutical products will be reimbursed. The Committee uses a stringent reference pricing system to establish the

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[20] Pharmaceutical Pricing and Reimbursement 2003 (Czech), at 41.
[21] World Health Organization, "Health Care Systems in Transition: The Czech Republic," World Health Organization Regional Office for Europe, Copenhagen 1996.
[22] Pharmaceutical Pricing and Reimbursement in European Union Ascension Countries (Czech), 44. (hereinafter Pharmaceutical Pricing and Reimbursement 2004).
[23] *Id.*, citing WHO figures in 2000.
[24] Pharmaceutical Pricing and Reimbursement 2003 (Czech), at 41.
[25] *Id.*

maximum reimbursement price of listed products. Under the system, there are 521 therapeutic drug groups based on the Anatomical Therapeutic Chemical (ATC) system. New drugs are usually reimbursed at the level of the cheapest available generic in the category. The system does not provide for consideration of the innovative/differential nature of a given product. New drugs also have prescription limits, *i.e.* these drugs can be prescribed by specialists only.

The categorization and reimbursement system is not applied in a consistent manner and transparency is lacking. The Czech system lacks objective and verifiable criteria for the inclusion and setting of reimbursement limits, individual communication with applicants, timeframes and legal remedies in case of appeal.

Delays are another significant issue plaguing the reimbursement system. Partly as a result of the lack of objective criteria for reviewing new medicines for inclusion, it is not uncommon for listing decisions to take years after registration of the drug.

Finally, the Czech Republic is also moving toward more widespread use of prescribing budgets for doctors.[26] The health insurers in the national system that currently use such controls generally penalize doctors for prescriptions exceeding their budget by 20%, or the amount of the previous year's expenditure.[27]

Research and Development:

There is no significant Czech R&D in pharmaceuticals. R&D by PhRMA Member Companies in Central and Eastern Europe more generally totaled US$ 91.4 million in 2002, or 0.3% of total global R&D expenditures.[28]

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[26] *Id.*, at 43.

[27] *Id.*

[28] The total R&D expenditures for Central and Eastern Europe includes the countries of Cyprus, Czech Republic, Estonia, Hungary, Poland, Slovenia, Bulgaria, Lithuania, Latvia, Romania, Slovakia, and Malta. PhRMA Profile 2004: Focus on Innovation, 42.

DENMARK

Health Care Financing:

Denmark provides healthcare coverage to all citizens through its national health insurance system administered at the regional level. Health care services are financed through regional taxation and patient co-payments.[29] In general there is free access to all hospital services as well as visits to general practitioners. Private insurance is also available for purchase by Danish citizens.[30] Around 1.7 million citizens are members of the private insurance company "danmark", that predominantly covers dentist services and pharmaceuticals. A large proportion of co-payments are covered by this supplementary private insurance.

Pharmaceutical Market:

In 2002, the Danish Pharmaceutical market was valued at US$ 1, 254 million. Per capita health expenditure equalled US$ 2, 595. Total healthcare expenditure as a percentage of GDP equalled 8.3%.[31]

Approximately 27% by value of the pharmaceutical market in Denmark is generic and 10% of the market is consists of lower cost parallel imported products.

Pricing, Reimbursement, Access:

The Danish Medicines Agency is responsible for pricing and reimbursing decisions in Demark which are based on recommendations from a reimbursement board (Medicintilskudsnævntet) consisting of seven appointees, mostly of whom are physicians.

Public reimbursement prices are based on an average of European price (AEP) levels. The average European price is calculated on the basis of prices with all EU/EEA countries except Spain, Portugal, Greece and Luxembourg. Companies are required to submit AEP pricing information to the Danish Medicines Agency every six months, and must notify the agency of price changes occurring in any of the reference countries, by contrast. The prices of generic pharmaceutical products are not regulated if such products are marketed only in Denmark.[32]

Reimbursement decisions are based on an evaluation of the product's price and therapeutic value. Reimbursement decisions in recent years have become increasingly politicized and lack of objective criterion. Whether for reasons of

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[29] Vallgårda, Signild, Krasnik, Allan, Vranbæk, Karsten, "Health Systems in Transition: Denmark" (Geneva: World Health Organization, 2001), Internet. Available at: http://www.who.dk/document/e72967.pdf.

[30] Pharmaceutical Pricing and Reimbursement 2003 (Denmark), at 46.

[31] *Id.*

[32] *Id.* at 48.

price or alleged lack of novelty, the Reimbursement Board has not hesitated to refuse reimbursement to a number of PhRMA member company's products, effectively denying them to Danish patients.

Since 1998, the Danish Government has also implemented a number of other measures to reduce spending on pharmaceuticals. These include temporary price ceilings and increasing consumer co-payments. On average, the government generally funds approximately 67% of the cost of pharmaceuticals, with the rest (33%) paid by consumers in the form of a co-payment. Actual consumer co-payment levels are calculated on an individual patient's level of consumption.[33] This "need-based" co-payment system was introduced in March 2000. Consumers with lower pharmaceutical expenses pay higher co-payments and consumers with relatively high expenses have lower co-payments. There are no co-payments for the medicines used in hospitals.

The government of Denmark controls approximately 90% of the Danish pharmaceutical market. In other words, about 90% of the consumption of prescription medicines is covered by the government, and are included on the reimbursement list.

Denmark is one of the few European countries to apply its standard VAT rate of 25 % to all pharmaceuticals.

Research and Development:

According to local sources in Denmark, the pharmaceutical industry in Denmark invests approximately DKK 6.5 billion (US$ 897 million) on research and development activities.

[33] *Id.*

FINLAND

Health Care Financing:

Universal health care is available to all citizens in Finland. The system is administered at the municipal level, and financing occurs through state and municipal taxation. Public health care covers in-patient medication. The National Health Insurance Scheme (NHIS) covers part of the costs of out-patient physician visits and out-patient pharmaceuticals.[34] Out-patient medicines are sold through privately owned pharmacies.

Pharmaceutical Market:

In 2003, the total pharmaceutical market at wholesale prices was valued at euro 1,503 million (US$ 1794 million) and the self-care market at € 174 million (US$ 207 million).

In 2001, total per capita healthcare expenditure equalled US$ 1,820, and health care expenditures represented 7% of its annual GDP. Out-patient pharmaceuticals represent 12.9% of the annual healthcare budget.[35]

The size of the generic market in Finland has been modest – approximately 3% of sales by value.[36]

Pricing, Reimbursement, Access:

Reimbursed pharmaceutical prices for both innovative and generic drugs are determined by the Pharmaceuticals Pricing Board (PPB) under the Ministry of Social Affairs and Health. The PPB establishes a maximum wholesale price of pharmaceuticals at which point a product automatically qualifies for basic (50%) reimbursement by the NHIS.

In establishing this maximum price, the NHIS considers cost effectiveness data, the price of the product in other EU countries, manufacturing and R&D costs, and funds available to the NHIS.

Once a new drug has received a price approval, it may also qualify for certain special reimbursement categories (75 or 100%). These categories are reserved for eligible patients suffering from certain chronic and/or severe illnesses. Most new drugs are still only eligible for special reimbursement after they have been

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[34] Pharmaceutical Pricing and Reimbursement 2003 (Finland), at 55. Järvelin, Jutta, "Health Care Systems in Transition: Finland" (Geneva: European Observatory on Health Care Systems, 2002).

[35] Social Insurance Institution and States, 2003.

[36] Pharmaceutical Pricing and Reimbursement 2003 (Finland), at 61.

available for two years in the basic reimbursement category (50%). In order to qualify for reimbursement at a higher rate, the company is required to complete a full pharmacoeconomic evaluation illustrating the product's therapeutic value and cost-effectiveness.

Price and special reimbursement decisions are valid for a period of up to three years for new chemical entities and up to five years for other products.

Patient co-payments are a significant feature at the Finnish System. Each year, patients are responsible for paying up to a fixed amount of the cost of pharmaceuticals; costs in excess of this limit are covered by the NHIS.[37]

Research and Development:

In 2002, pharmaceutical research and development investment in Finland was € 252 million (US$ 300 million), of which clinical trials accounted for € 90 million (US$ 107 million).[38]

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[37] *Id.*, at 54-60.

[38] Pharmaceutical Industry Finland, RM Surveys 1996 – 2003.

FRANCE

Health Care Financing:

The French National Health system covers virtually the entire French population. The system is administered by several Government agencies and funded by the Social Security program, which in turn is funded by compulsory payroll taxes paid by employers and employees. The Social Security program covers approximately 74% of health care expenditures, with the remaining 26% funded by patient co-payments.[39]

Pharmaceutical Market:

In 2003, France's pharmaceutical market was valued at approximately € 20 billion (US$ 24 billion). In 2001, total health spending per capita equaled € 2, 093 (US$ 1, 793) with € 448 (US$ 357) spent on pharmaceuticals. Pharmaceuticals represented 21.4% of total health care expenditures in France in 2001. More than 90% of total sales are reimbursable drugs.[40]

Generic drugs have historically comprised a small percentage of the French market, estimated at 4% by value and 8% by volume at the end of 2001.[41] Policy changes introduced in 2003, however, have resulted in a significant increase in the market over the past year.[42]

Pricing, Reimbursement and Access:

As part of a broader plan to reduce the budget deficit, France has adopted several recent laws and regulations to limit Social Security expenditures on pharmaceuticals. These measures restrict not only overall drug spending, but also individual company sales, promotion expenses, therapeutic class sales, and specific product sales.

In France, the government "Transparency Committee" is responsible for determining whether pharmaceutical products will be included on the government reimbursement list. To apply for reimbursement for a new drug, companies must submit extensive scientific dossiers to the Transparency Committee. If accepted, a drug is either reimbursed at a 35%, 65% or 100% level, depending primarily on the severity of the condition it is intended to treat and its efficacy.[43] The Transparency Committee's assessment of the product is then passed to the Economic Committee on Health Products (CEPS) which negotiates the price with

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[39] ITC Pricing Report, at 4-16.
[40] LEEM, "Key Facts : Drugs, Healthcare, Economy" 2003.
[41] Pharmaceutical Pricing and Reimbursement 2003 (France), at 70.
[42] LEEM, January 2004.
[43] *Id.*; ITC Pricing Report, at 4-18.

the manufacturer. In these negotiations, the French government generally insists on a price/volume agreement with the manufacturer involved, as well as mandatory rebates for sales that exceed the agreed volume level. The framework agreement under which such negotiations take place is known as the Accord-cadre and was renewed in June 2003. Pharmaceutical companies have little choice but to accede to the government's demands in these negotiations because failure to do subjects them to a special tax known as the "Safeguard Clause."

Every year a Social Security Financing law is approved by Parliament and fixes a goal for pharmaceutical expenditure levels. When government spending on pharmaceuticals exceeds these targets, the government imposes on the pharmaceutical industry a tax known as the Safeguard Clause. The targets established by the Parliament are invariably unrealistic and are regularly exceeded by the government, triggering the Safeguard Clause. The amount of this tax can reach 70% of the "overspending." The only way for companies to avoid this punitive tax is by "voluntarily" entering into a price agreement with the CEPS in which they commit to pay significant rebates to the government and agree to volume limitations on their sales.

Such caps on sales growth disproportionately harm the innovative pharmaceutical industry in France. Innovative drugs tend to have the highest growth rates, as they first come on the market and doctors learn about the new treatment. Drugs with rapid sales growth, however, are the most significantly affected by volume restrictions.

In addition to these measures, the French government imposes a significant tax on pharmaceutical company promotional expenses. In 2003, that tax was estimated at € 243 million (US$ 293 million). The French Social Security Financing Law for 2004 adopted a € 50 million (US$ 60 million) increase in the tax and set up an additional € 100 million (US$ 120 million) tax that could be implemented in 2005.

On the positive side, in 2003, a fast track procedure, called "depot de prix" was adopted in France. It gives the possibility to a firm, for its most innovative products (as determined by the Transparency Committee) to propose a price that is accepted or rejected by CEPS within 2 weeks. It is too early to assess the real effect of this reform, and whether it will actually operate to provide greater incentives to market innovative drugs in France.

Wholesale, pharmacy and hospital margins are also controlled in France.

Research and Development:

In 2000, the pharmaceutical industry spent € 3,338 million (US$ 4, 036 million) on research and development activities in France.[44]

A study by Agipharm in 2002,[45] found that France, with one of the strictest price control regimes in Europe, has witnessed a sharp decline in recent years in the number of innovative medicines developed in the country. Reportedly, the French government is studying ways to reverse this decline.

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[44] "Key Facts : Drugs, Healthcare, Economy" – LEEM 2003

[45] Agripharm,"Les investissements des laboratoires pharmaceutiques Nord-américains en Europe : quelle place pour la France?" (November 2002).

GERMANY

Health Care Financing:

Health care in Germany is provided for over 90% of the population by non-profit sick funds *(Krankenkassen)* that are funded by a compulsory payroll deduction and to a small extent by general taxation revenues. There are a large number of sick funds organized along local, company, occupational or national lines. It is possible for Germans whose earnings exceed a certain threshold amount to opt out of the system and purchase private insurance.

Pharmaceutical Market:

Germany is Europe's largest pharmaceutical market and the third largest market in the world after the United States and Japan, valued at € 30,100 (US$ 36,399) million in 2001. Drugs reimbursed by sick funds represent 78% of the market. In 2000, American research-based pharmaceutical companies represent 22% of the total turnover in Germany. Total health care expenditures per capita in Germany totaled US$ 2,504. Total healthcare expenditure as a percentage of GDP equaled 10.6%.[46]

Germany has one of the largest generic markets in Europe, with generics accounting for 28.5% by value of the total pharmaceutical market in 2001.[47]

Pricing, Reimbursement and Access:

For the last several years, Germany has maintained a two-tiered reimbursement system that uses both reference pricing and free market pricing. Under the system, prices for off-patented products are determined by reference to generic products. The exact formula used to determine these prices is complicated, but in principle, it requires for multi-source products that a drug should not be priced higher than the upper limit of the lower third of the existing product price range for the appropriate product grouping in Germany.[48]

Until this year, patented drugs approved after December 31, 1995, were exempt from the reference pricing system and allowed to be priced in accordance with market conditions. New legislation went into effect on January 1, 2004, however, pursuant to which the sick funds have the authority and plan to establish reference prices for all new pharmaceutical products including patented ones. This same legislation also provided that OTC products are generally excluded from reimbursement.

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[46] Pharmaceutical Pricing and Reimbursement (Germany), 74.
[47] *Id.*, at 81.
[48] ITC Pricing Study, at 4-22.

Industry payback arrangements have been used by the German government with increasing frequency. German legislation requires a 6% rebate paid by pharmaceutical companies to the sick funds on sales of non-referenced products. As of January 1, 2004, this mandatory rebate was raised to 16% effective until the end of 2004.

Germany has also relied on prescribing controls imposed on doctors to reduce pharmaceutical sales. At the regional level, doctors are set individual spending targets based on the average prescribing costs per patient per year for each physical specialty.[49] Doctors exceeding their targets will incur audits, additional controls, and in some cases an obligation to repay the "excess." These strict budgetary controls mean that German physicians may not always be in a position to prescribe the products that, in their professional opinion, would best suit their patients' needs. In some cases, only patients who specifically request innovative products may receive them, while those who do not are prescribed older, less effective medicines. The impact of these government-set doctor budgets clearly biases physicians' decision-making away from innovative therapies, which in turn translates into a bias against many American pharmaceuticals.

The full VAT of 16% is imposed on drugs. Until the end of 2003 markups for pharmacies and wholesalers and VAT accounted for 45% of the average retail price of pharmaceutical products. As of January 1, 2004, this system was amended; pharmacists now receive a flat rate (€ 8.10) for their services plus 3% of the drug price.

Research and Development:

In 2002, R&D of ethical pharmaceuticals by PhRMA Member companies in Germany totaled US $ 401.2 million, or 1.3% of those companies' global R&D expenditures.[50]

The imposition of reference pricing in Germany in 1989 had a significant negative impact on investments in research and development. During the five-year period from 1989 to 1995, during which reference pricing was in effect for all products, R&D fell by 13% in Germany. In 1996, recognizing the negative impact of reference pricing on innovation, Germany amended its policy to exclude from the reference pricing system patented products registered on or after January 1, 1996. Since then, the investment climate for the research-based industry in Germany has improved and more research is taking place. Between 1996 and 1998, total research and development expenditures in Germany rose by 12% and now total over € 3.6 billion (US$ 2.5 billion). PhRMA members are extremely concerned about the new reference pricing law that went into effect in early 2004, and fully expect that if implemented, the return to broad reference pricing will once again have a strong negative effect on the R&D climate in Germany.

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[49] Pharmaceutical Pricing and Reimbursement 2003, at 80.

[50] PhRMA Profile 2004: Focus on Innovation, 42.

GREECE

Health Care Financing:

The Greek health care system can today be characterized as a mixed system: the health care branches of various social insurance funds co-exist with the National Health System (NHS). As far as funding is concerned, the NHS is primarily funded by taxation and social insurance (56.3% of total expenditure in 2000). Payments from private health insurance account for 2.3% of the funding and out-of-pocket payments from patients account for the remaining 41.4%.

Approximately 95% of the Greek population has supplemental health insurance. The four largest sick funds are the Institute of Social Insurance (IKA); the Organization of Agricultural Insurance (OGA); the Fund for Merchants, Manufacturers and Small Businessmen (TEVE); and the Fund for Public Servants (OPAD). These funds provide for the reimbursement of primary, secondary, pharmaceutical and dental care, and in some funds, reimbursement for diagnostic and laboratory tests. Financing of health insurance is provided in part by employer contributions, general taxation and patient co-payments.[51]

Pharmaceutical Market:

For 2002, total health expenditure in Greece was €13.46 billion (US$ 16.28 billion) or 9.5% of GDP. Expenditure on pharmaceuticals in 2002 reached €2.061 billion or 15.3% of total health expenditure.

In 2002, the market share of imported products was 68% in Greece. The market share of locally produced and packaged medicinal products was 21% and 11%, respectively.

Pricing, Reimbursement, Access:

The Directorate of Prices and Medicinal Products in the Ministry of Development sets pharmaceutical prices in Greece. According to Market Decree 14/89, separate pricing procedures apply to imported and domestically produced pharmaceuticals. For imported products, the lowest ex-factory European price applies. For products manufactured or packaged domestically, production and distribution cost factors are taken into account. The derived price is verified against the price of the same product in other European countries and the lowest is applied, plus a profit margin of 8.5%.[52]

A three-year monitoring period applies after a price is set for a specific product. If a lower price is recorded in Europe during this period, the maximum

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[51] Pharmaceutical Pricing and Reimbursement 2003 (Greece), at 85.

[52] *Id.*

permissible price of the product in Greece is reduced accordingly; however, if the initially lower price in Europe is raised such an adjustment in the price of the new product does not apply in Greece. Pharmaceutical products that are viewed as necessary for public health by either the Ministry of Health or the National Drug Organization are exempt from the above procedures.

The prices of generics are set at 80% of the retail price of the respective original product. In light of the relatively low prices of branded products and the relatively high prices of generics, the generics segment represents only 10.6% of the total market value in Greece (2002 data).

The prices of over-the-counter pharmaceuticals are regulated in Greece as well. The criteria for calculating the prices of OTCs are the same as those used for calculating the prices of prescription-only products.

The Government of Greece uses a positive listing scheme to determine eligibility for pharmaceutical reimbursement. Products must satisfy several criteria in order to be listed, such as efficacy, tolerance and safety of the product in comparison to other products already listed the average cost of daily treatment, reimbursement by other European countries, and other information. Since October 2003, these criteria have been expanded to place greater emphasis on pharmacoeconomic analysis of the product.

Delays in the reimbursement process are a major market access barrier in Greece. Greece so far has not being able to complete and publish reimbursement decisions within the legal timeframe as stipulated by the EU Transparency Directive 89/105. [53]

The rate of co-payment for a prescription drug is uniform for all insurance funds in Greece and set at 0%, 10% or 25%, depending on the disease and population groups. Specific pharmaceutical products can only be dispensed from public hospitals' pharmacies. These products are fully reimbursed by social insurance.

Research and Development:

No significant pharmaceutical research is carried out in Greece. There is some limited development work in the form of clinical trials usually carried out by foreign pharmaceutical companies. There are no figures available for R&D investment.

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[53] *Id.*, at 85-87.

HUNGARY

Health Care Financing:

Health care coverage is universal in Hungary. Financing of the health care system occurs through a mixture of the National Health Insurance Fund and state taxes. Funding of the Health Insurance Fund occurs through both employer and individual contributions. The Health Insurance Fund collects revenues centrally through the government and allocates funds to the different types of services and resources and then to the county level.[54] Delivery of services occurs at the county and municipal levels.[55]

Pharmaceutical Market:

In 2002, the Hungarian pharmaceutical market was valued at US$ 1206 million. Per capita healthcare expenditure totaled US$ 315. Total healthcare expenditure as a percentage of GDP equaled 6.8%.[56]

Pricing, Reimbursement and Access:

The Ministry of Health is the main regulatory body of the healthcare system.[57] The National Institute of Pharmacy and the National Institute of Hospital and Medical Technology share registration and licensing oversight of pharmaceutical products.

Hungary operates a positive list of pharmaceuticals that is reimbursed through the national system. (A separate list is maintained for indigent patients.) Reimbursement of pharmaceutical products occurs at either a 0, 50, 70 or 90 per cent rate.[58] The system for determining which products are included on the positive list and the level of reimbursement for those products is highly non-transparent in Hungary,[59] and frequently manipulated to favor local generic producers.

Prior to 2000, prices for reimbursed products were determined in Hungary, at least in part, by individual company negotiations with the Hungarian government. In 2000, the Hungarian government instituted a price freeze on all medicines. In 2001, the government approved a pricing framework whereby prices would be allowed to rise slightly every year, but it was later abrogated and the price freeze reinstated. At present, the Government of Hungary is seeking to impose a new four-year plan for controlling pharmaceutical prices. In March 2004, the

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[54] Ferguson, Shannon C, and Ben Irvine, "Background Briefing: Hungary's Healthcare System"

[55] *Id.* Gaal, P., Rekassy, B., and Healy, J., "Health Care Systems in Transition: Hungary" Copenhagen: European Observatory on Healthcare Systems, 1999.

[56] Pharmaceutical Pricing and Reimbursement (Hungary) 2004, 67.

[57] Ferguson and Irvine.

[58] Gaal, Rekassy, and Healy.

[59] Pharmaceutical Pricing and Reimbursement (Hungary) 2003, at 99-100.

government abruptly imposed an across-the-board 15% price cut on all pharmaceuticals.

PhRMA members are concerned the Hungarian government's new initiative to control pharmaceutical spending will not adequately guarantee access to the market for innovative pharmaceutical products. A new proposal states only that ministerial decrees will form the legal framework for market access of new products in the future, but does not provide any details regarding access of new products to the reimbursement lists or government pricing policies.

The Government of Hungary instituted a number of other changes to the pricing and reimbursement system in 2003. Although the legal authority for it is unclear, a new price-volume system was introduced that applies to certain product classes, and includes a therapeutic reference pricing system. Under this system, only the two least-expensive products within the same Anatomical Therapeutic Chemical (ATC) class will be reimbursed. The Government has also implemented a policy of delisting products from reimbursement without consultation or notice.

As mentioned, in 2004, the Government imposed an across the board 15% price reduction for reimbursed and non-reimbursed pharmaceuticals. This manner in which this cut has been implemented discriminates against multinational and innovative pharmaceutical companies. The 15% price cut does not apply to products under 600 HUF (approximately $3). On the contrary, the Hungarian Government recently allowed a 20% price increase for these medicines priced less than 600 HUF. This group of products, priced at less than 600 HUF, represents 43% of local company sales in 2003 and only 15% of multinational company sales.

The lack of transparency generally plaguing the Hungarian system is particularly evident with respect to this new price-volume system and therapeutic reference pricing system. There are many unclear and unpublished details regarding price volume contracts -- *e.g.*: the reason for a contract, which product(s) or product group(s) are to be covered by the contract, the way the budget is decided, and the method of repayment.

The situation is similar regarding the new therapeutic reference pricing system. There is no clarity on the criteria for inclusion, which product(s) or product group(s) are to be included, the reference price, the reference price level/range, the reference product, or the method of calculation. In addition, there is no appeal procedure.

A lack of transparency is also evident in the case of the positive list for indigent patients (Közgyogy) that affects approximately six percent of the population but represents 20% of total pharmaceutical demand. Indigent patients receive all medical care, including pharmaceuticals, free of charge. The list contains all

categories on the general positive list, as well as additional categories that are not reimbursed through the general list.

The vast majority of the products on the Közgyogy list are locally produced. Even when an imported product is available at equal or lower price, preference is given to the local one. Additional products – not reimbursed through the general list – are exclusively locally produced. Companies are not informed about the reasons for non-inclusion of their products and no appeal procedure is available.

Research and Development:

R&D expenditures of U.S. pharmaceutical companies in Central and Eastern Europe totaled US$ 91.4 million in 2002, or 0.3% of global R&D expenditures.[60]

[60] PhRMA, Profile 2004: Focus on Innovation. 42. The total R&D expenditures for Central and Eastern Europe includes the countries of Cyprus, Czech Republic, Estonia, Hungary, Poland, Slovenia, Bulgaria, Lithuania, Latvia, Romania, Slovakia, and Malta.

ICELAND

Health Care Financing:

The Government of Iceland provides universal healthcare to its citizens through a compulsory health insurance scheme. Delivery of healthcare services occurs regionally at 83 health centers throughout the country. The system is financed through national taxation. Patient co-payments are mandatory for services requiring a specialist and for pharmaceuticals.[61]

Pharmaceutical Market:

Total healthcare expenditure as a percentage of GDP in Iceland equaled 8.0% in 2001.[62]

Pricing, Reimbursement, Access:

Reimbursement of pharmaceuticals in Iceland is based on the severity of disease treated and frequency of use of the drugs. The Government of Iceland reimburses drugs for severe and chronic diseases at 100%. Short-term treatments such as antibiotics are not reimbursed. Pharmaceuticals outside of these categories are reimbursed by the Government of Iceland after the patient pays a fixed percentage of the cost of treatment.[63]

Research and Development:

No data available.

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[61] World Health Organization, "Highlights on Health in Iceland", http://www.who.dk/document/E72496.pdf, at 27.

[62] *Id.*

[63] *Id.* at 28.

IRELAND

Health Care Financing:

Access to the Ireland's public healthcare system is means-tested based on income. Those citizens who fall below a certain income level are classified into Category I (Medical Card Holders), and have full access to the healthcare system, including pharmaceutical products, free of charge. Those earning more than the set income level are classified into Category II (Non-Medical Card Holders). They are entitled to free access to public hospitals but they contribute to primary care physician costs and treatment in public hospitals through government-sponsored voluntary health insurance, private insurance or direct payments.[64] Financing of the public healthcare system occurs through a mixture of public funding, private insurance, and patient contributions.[65]

Pharmaceutical Market:

According to figures from the Irish Health Ministry, total healthcare expenditure amounted to €12.30 billion (US$ 14.874 billion) in 2002. These expenditures were comprised of 81.5% Government expenditure and 18.5% private expenditure. Total healthcare expenditure as a percentage of GDP amounted to 8.1%.

The total prescription pharmaceutical market in 2002 at trade prices (cost to retailer before retail markup) was worth $850 million and $1.017 billion in 2003. Generics amounted to $59 million or 6.9% of that market in 2002, and $65 million (6.4%) in 2003. Over 90% of the generic market consists of branded generics.

Pricing, Reimbursement and Access:

Ireland uses a number of policies to control pricing, reimbursement and access to medicines including reference pricing, price freezes, patient co-payments, pharmacoeconomic evaluations of new chemical entities, and physician prescribing budgets.

Ireland maintains a positive list of reimbursable drugs (known as the GMS Code Book) and manufacturers must submit an application to the Department of Health to have their products included on the list.

Under Ireland's reference pricing system, the average wholesale price of new medicines must not exceed the lower of either the UK wholesale price or the average wholesale price in Denmark, France, Germany, the Netherlands and the UK. If the product is not available in any of these reference countries, the

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[64] World Health Organization, "Highlights on Health in Ireland", www.who.org.

[65] Ireland Department of Health, New Health Strategy "The Health System Explained".

product's wholesale price is determined through a negotiation between the Department of Health and the manufacturer or importer of the product.[66] Prices for generic medicines are determined in the same manner as prices for prescription products, and typically range between 20-40% below the original product prices.[67]

Reimbursement price levels, once set, are not allowed to rise in Iceland. A price freeze has been in effect since 1992.

The Department of Health reserves the right to seek cost benefit studies for any new drug introduced into the Irish market after 1st August 1997, but cannot delay the access of the drug to the reimbursement lists while such studies are conducted.

Doctors are able to prescribe the medicines of their choice from the state reimbursement list. Pharmacists are required to dispense to patients the medicines prescribed by doctors. The Department of Health, however, reserves the right to influence the prescribing habits of doctors and has sought to do so by encouraging (but not requiring) doctors to prescribe generically.

The Department of Health has, for a number of years, implemented a policy of establishing drug budgets for general practitioners for their medical cardholder patients. A proportion of the amounts saved on these budgets (originally 50%, more recently 100%) is refunded to doctors through their local health boards, and may be used by them to enhance their practice facilities or services.

Finally, Ireland has also insisted on various industry payback arrangements. At present, manufacturers must give a rebate to the General Medical Services (Payments) Board of 3% of the value of products dispensed to medical card patients (approximately 66% of all prescribing).

Research and Development:

Research and development expenditure by the pharmaceutical industry in 2002 amounted to approximately €85 million (US$ 103 million) in Ireland.

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[66] Pharmaceutical Pricing and Reimbursement 2003 (Ireland), at 102; Mc Guinn, T., and Troy, J., "Ireland: Pharmaceutical Pricing and Reimbursement" Department of Health and Children, Government of Ireland.

[67] Pharmaceutical Pricing and Reimbursement (Ireland) 2003, at 102.

ITALY

Health Care Financing:

The Italian National Health Service (Servizio Sanitario Nazionale - SSN) guarantees universal coverage of the population. Italian citizens are permitted to obtain private health insurance coverage, but must still pay taxes to support the public system.

The system in Italy is highly decentralized. Health care is administered through 197 regional health authorities (known as ASLs).[68] Since 2001, SSN funding has been based exclusively on regional taxation. The regional ASLs are been empowered to decide how to allocate healthcare resources (*i.e.*, to determine levels of spending on drugs vs. spending on hospitals, diagnostics, physicians' fees, etc.), provided they ensure that healthcare expenditures as a whole are not lower than an amount determined by national authorities for each Region. Thus, there are differences by region in budgetary priorities and provision of healthcare services.

Pharmaceutical Market:

The Italian pharmaceutical market was valued at US$ 11,825 million in 2001[69], of which U.S. research-based pharmaceutical companies represented approximately 27% of the total turnover. Total health care expenditures in Italy totaled € 110.98 billion (US$1,315.889 billion), or 8.2% as a percentage of GDP in 2003. Of the €110.98 spent on healthcare, public healthcare expenditures totaled € 85.55 (US$ 10.143) and private healthcare expenditures totaled € 25.43 (US$ 3,015.24).[70]

Historically, generic drugs have represented a small percentage of the Italian market, approximately 3%.[71] The generic market has expanded in recent years to approximately 12%, however, due to the pricing strategies of the Italian government.

Pricing, Reimbursement and Access:

Italy maintains a positive reimbursement list (Prontuario) at the national level. In 2003, the Drug Approval Committee (CUF) revised the Prontuario and introduced an ATC/DDD-based reference price system for patented products. A new law passed in the fall of 2003, Law 326/2003, however, could result in major structural changes to the Italian pricing and reimbursement system. The new law requires the establishment of a new Medicines Agency to replace the CUF. The

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[68] Minister of Health, DG Information Systems, Office of Statistics – 2002 data.
[69] Pharmaceutical Pricing and Reimbursement 2003 (Italy), at 109.
[70] Local industry statistics.
[71] Pharmaceutical Pricing and Reimbursement 2003 (Italy), at 118.

new Agency will have responsibility for all pharmaceutical-sector matters, including drug approvals, pharmacovigilance, pharmaceutical spending, pricing and reimbursement. The Italian Government is still in the process of organizing this new agency. The President, Director General and Board of Directors were appointed on April 29th. The organization process is likely to continue at least through the end of the summer 2004.

Law 326/2003 also mandated substantial revisions to the pharmaceutical pricing regulations. Prior to January 1, 2004, Italy had priced certain types of drugs on the basis of the European Average Price for those drugs. The new law eliminated any reliance on EAP in setting drug prices for the Italian market. Instead, Italy will negotiate the prices of reimbursed products by reference to the government's determination of a drug's added therapeutic value compared to all drugs belonging to the same therapeutic class. A Prontuario revision, based on cost-effectiveness criteria, will be conducted at least annually (by Sept. 30th), or twice a year if spending on products on this list exceeds expectations. The regulations governing this new pricing procedure have not been issued, and there is a significant lack of clarity at present regarding the manner in which the new standards will be implemented by the new agency.

In the past, and notwithstanding its formal procedures for establishing pharmaceutical prices for individual products, Italy has also imposed periodic across-the-board cuts in the prices of all reimbursed pharmaceutical products. A 5% cut of reimbursed drugs' prices was mandated in 2002 by Law 112/2002, and an additional 2% across-the-board cut was implemented in January 2003 as a result of the 2003 Financial Act.

Law 326/2003 also established a ceiling for pharmaceutical spending. Pharmaceutical spending at the pharmacy level cannot exceed 13% of 2004 healthcare expenditures (and/or 16% including hospital sales). If these ceilings are exceeded, the "excess" amount that the government spent on pharmaceutical purchases for Italian patients must actually be paid by the pharmaceutical industry (60%) and the Regions (40%). These "payback" provisions are a significant concern for the industry. Notably, local Italian interests, such as pharmacists and wholesalers/distributors, are not subject to the payback requirements under the new Law.

Law 326/2003 also imposed additional burden on pharmaceutical manufacturers. Under the law, pharmaceutical companies will have to pay an annual "contribution" to the Italian state equal to 5% of their promotional spending for physicians, health professionals and pharmacists.

Research and Development:

In 2002, R&D expenditures by U.S.-based pharmaceutical companies in Italy totaled US$ 232.2 million.[72]

[72] PhRMA, Profile 2004: Focus on Innovation, 46.

JAPAN

Health Care Financing:

Japan provides universal healthcare to its citizens through the National Health Insurance (NHI) system. The system is funded by a comprehensive fee-for-service schedule. For pharmaceuticals, only products in the NHI tariff lists can be prescribed, with reimbursement limited to listed tariff rates.

Virtually everyone in Japan is insured under one of several compulsory medical insurance schemes, which are both publicly and privately run. The insurance plan under which families are covered is determined by the main breadwinner's employment status. For example, there are different schemes covering employees in the private sector, compared with employees in the pubic sector.

Beginning in April 2004, health insurance premiums in Japan changed to 8.2 % of total annual income, resulting in all overall increase in out-of-pocket costs for citizens. In addition, a co-payment of 20-30 % contributes significantly to healthcare finances. Taxes, government subsidies and transfers among different insurance schemes are also important financing mechanisms.

The burden of healthcare costs will grow significantly in the future as Japan's population ages. For patients willing to take greater responsibility for the costs of care, private insurance may be a source of additional resources for the system. In that regard, a further option for supplemental payments or a private supplemental insurance program probably will need to be considered as part of a comprehensive reform plan in Japan in the future.

Pharmaceutical Market:

Japan is the world's second largest national pharmaceutical market after the United States. For the twelve month period ending in November 2003, Japan's pharmaceutical market was valued at US$ 51.1 billion. U.S. companies posted annual sales of US$ 9 billion, or 17% of the market share.[73] The share of pharmaceuticals in national health care expenditures dropped from 29.5 to 19.6 percent from 1990 to 2000 and remains flat in nominal terms.

The market share of generics in Japan is about 7 %. Generics prices will be set at 70 % (down from 80%) of the prices of brand products beginning in April 2004.

Pricing, Reimbursement and Access:

After gaining regulatory approval for a new drug in Japan, a pharmaceutical manufacturer begins the reimbursement process by filing an application for inclusion in the NHI price list. After the application has been completed, the

[73] IMS Health Data World Pharmaceutical Market Summary Issue 01/2004, at 1.

manufacturer meets with The Economic Affairs Division of the MHLW Health Policy Bureau, which reviews the submission with the company. The Medical Economic Division of the Health Insurance Bureau then examines the application and is responsible for proposing a price to the Drug Price Organization (DPO). The DPO makes an initial decision and informs the manufacturer of the proposed price within 90 days. Once the final price has been determined, the DPO informs the Central Social Insurance Medical Council (Chuikyo) of its decision on whether to include the product on the NHI price list. When a new product is included in the NHI Drug Price List, it can be reimbursed by the health insurance system.

The Ministry of Health Labor & Welfare (MHLW) uses a comparator pricing system to determine pharmaceutical prices. Under this system, prices are set by reference to a similar product already established in the market, the price of which has already been reduced under the "biennial system". To account for anomalies created from using old comparator products, the Government of Japan uses a Foreign Price Adjustment Rule based on prices in the United States, Germany, the United Kingdom and France.

The Government of Japan uses a biennial price reduction scheme on all pharmaceutical products. In other words, the government reviews and cuts the prices of all pharmaceutical products in the market place every two years. While the "biennial price reductions" scheme was originally devised to reduce the financial incentive for doctors to both prescribe and dispense pharmaceutical products, additional repricing rules have been added that target successful, innovative pharmaceutical products. For example, new products whose sales either exceed their original sales forecasts, products that have been approved for new indications that would expand their usefulness for additional patient populations, and products approved for use in combination with another drug are subject to "special repricing" every two years. Although this rule was not applied systematically during the 2004 biennial price reductions, the "repricing rule" remains available to the government as a mechanism to contain costs.

Japan's NHI systematically discourages innovation by setting low initial prices for innovative products, and further reducing those prices over the life of the product. The core of PhRMA's advocacy in Japan has been to reverse this bias.

Research and Development:

R&D of ethical pharmaceuticals by PhRMA member companies in Japan totaled US$ 706.4 million in 2002,[74] which is about 11% of all pharmaceutical R&D expenditure in Japan.

[74] PhRMA Profile 2004: Focus on Innovation, at 42.

KOREA

Health Care Financing:

Since 1989, Korea's National Health Insurance (NHI) system has provided universal coverage to 97% of Korean citizens. The system is financed through a combination of mandatory employer/employee contributions, contributions from the self-employed, general tort revenue and other subsidies. A prescription drug benefit is provided by the government for most medicines.

Health care is delivered primarily through private sector hospitals under fee for service contracts with the National Health Insurance Corporation. Within the health care system, patients have virtually no constraints on their choice of physicians. While the NHI system covers a majority of health benefits, out of pocket payments are relatively high due to the exclusion of "high cost" services and significant co-payments.[75]

The expansion of services, high demand for new medical technology, rapidly implemented reform measures and chronic under funding have contributed to a significant NHI budget deficit.[76] These budgetary pressures have led to the Ministry of Health and Welfare to implement a range of new cost containment policies. Moving forward, the sustainability of the Korean healthcare insurance scheme will require a more systematic reform plan.

Pharmaceutical Market:

Korea is one of the largest pharmaceutical markets in Asia, totaling about US$ 5.0 billion. In 2002, the market share of U.S. and European research-based companies was 31%. Total healthcare spending as a percentage of GDP equaled 5.9% in 2000.[77]

Pricing, Reimbursement and Access:

During the period 1999-2003, the Government of Korea implemented major reforms on its pricing, reimbursement and access policies which have had a significant impact on the research-based industry.

To determine the permissible introductory price of innovative medicines, the Government utilizes a system called "A7 pricing." Under the A7 policy, the price for new products is calculated by taking the average price of innovative medicines in seven advanced industrialized countries. The research-based

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[75] OECD, "Review of the Korean Health System", Ad Hoc Group on the OECD Health Project, at 14 (April 12, 2002).

[76] IMS Market Prognosis Asia, Korea 2003.

[77] PhRMA Profile 2004: Focus on Innovation, at 42.

industry is concerned by a lack of transparency and evidence-based decision making in the implementation of A7 pricing guidelines.

The Ministry of Health and Welfare has also implemented a triennial repricing scheme that recalculates the price of innovative medicines based on changes in prices in the "A7" countries. Rather than appropriately recalculating prices, however, only downward adjustments are applied. Therefore this regulation does not serve as a mechanism to reassess the price of innovative medicines in an objective fashion, but rather it is only a mechanism to reduce prices.

Pricing policies for medicines in Korea also provide disproportionate incentives for generic products. Medicines that have demonstrated bio-equivalency are automatically priced at a full 80% of the price of the originators' product. Generic products are primarily manufactured by Korean companies.

Korea's Actual Transaction Pricing System (ATP) is designed to remove the profit incentive for purchasing pharmaceuticals by medical institutions. Under the ATP system, pharmaceuticals are reimbursement at the average wholesale price. The principles behind the ATP system support acquisitions based on the value of innovative medicines. However, experience shows significant flaws in its operational guidelines and implementation. This has resulted in non-transparent, arbitrary price reductions and legal challenges by U.S. companies.

The reimbursement system is also operated by the Ministry of Health and Welfare, the Health Insurance Reimbursement Agency and a wide range of internal committees. This system is complex and non-transparent, and offers limited opportunity for consultation with stakeholders. Increasingly, reimbursement guidelines are based on arbitrary cost containment goals rather than scientific recommendations and sound medical and therapeutic practice. These reimbursement restrictions are applied most frequently to new products or therapeutic classes, which disproportionately impacts research-based companies. More importantly, these restrictions significantly limit or delay patients' access to innovative medicines.

A significant reform affecting access to innovative medicines was the separation of prescribing and dispensing of pharmaceuticals (SDP) in 2000. SDP removed the profit motive from prescribing decisions. Eliminating financial incentives in prescribing patterns also increased patient awareness and utilization of innovative medicines.

The Ministry of Health and Welfare is currently evaluating the use of pharmacoeconomic data in pricing and/or reimbursement decisions. Industry is very concerned about the structure and application of pharmacoeconomics in Korea, as it has often been used as an access barrier in other OECD countries.

Research and Development:

No data is available on pharmaceutical R&D levels in Korea.

LUXEMBOURG

Health Care Financing:

Luxembourg provides compulsory health insurance to approximately 99% of its citizens. Health insurance is managed through the Union of Sickness Funds and financing occurs through a combination of government contributions, employer contributions and individual contributions. Generally, healthcare services are provided on a fee-for-service basis with payment of these services occurring through a combination of reimbursement by the sickfund and patient co-payments.[78]

Pharmaceutical Market:

PhRMA does not have separate data on the Luxembourg market.

Pricing, Reimbursement, Access:

Luxembourg is a net importer of pharmaceutical products from Belgium, France and Germany. The Directorate of Health uses a positive list scheme for pricing and reimbursement of pharmaceuticals. The list serves as a national formulary and guide to reimbursement. Generally, reimbursement prices are established by the government on the basis of those prices used in the country of origin of the imported drug. Through this mechanism, price controls imposed in other European markets have a direct effect on the market in Luxembourg as well.

Luxembourg's listing scheme is divided into four reimbursement rate categories: normal rate 80%, preferential rate 100%, reduced rate 40%, and no reimbursement. Most drugs are reimbursed at the normal rate. Drugs for serious, long-term chronic diseases are reimbursed 100%, while medicines designated as "comfort" drugs, such as painkillers receive, a 40% reimbursement rate.

Patient co-payments for pharmaceuticals average approximately 20% of the retail price.[79]

Research and Development:

Data not available.

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[78] Elizabeth Kerr, "Health Care Systems in Transition: Luxembourg" (Copenhagen: European Observatory on Health Care Systems, 1999) accessed on February 24, 2004 at http://www.who.dk/document/e67498.pdf, at 9, 17-19.

[79] Kerr, at 19, 48-49.

MEXICO

Health Care Financing:

Mexico has recently undertaken substantial reforms to decentralize its healthcare system and significantly expand coverage. There are two kinds of programs in the public sector: the new Popular Health Insurance program and various established social security programs. The Popular Health Insurance (SPS in Spanish), is a large-scale pilot program. In this program, funding is drawn from the federal and state governments, as well as participating families. State governments promote affiliation with SPS, and there is an enrollment fee for participants. Once the family is enrolled, the federal government transfers its contribution to the state. Enrolled families have access to a predetermined and relatively restricted health package, including some pharmaceutical coverage. Restrictions differ by state, but generally patients cannot go to a private hospital or clinic.

In addition to the SPS system, Mexico provides public healthcare through the social security system. Primarily, the social security system works through two programs: the Instituto Mexicano de Seguro Social (IMSS), which provides healthcare to employees in the private sector and to the poor, and the Social Security Institute for State Employees (ISSSTE), which serves federal employees. Financing of IMSS and ISSSTE occurs through a mixture of government, employer and employee contributions. Employees in the national oil company and the military have separate healthcare systems financed by government contributions and co-payments. There is also a specialized system focusing on children's health.

Private insurance is available for purchase and is relied upon by some Mexican families as either an alternative or a complement to the existing schemes. However, private insurance covers less than 10% of the population.[80]

Pharmaceutical Market:

Mexico is the largest market for pharmaceutical products in Latin America. Pharmaceutical sales in Mexico totaled US$ 6.1 billion during the twelve month period to November 2003.[81] Per capita health spending in Mexico totaled US$ 483. Total healthcare spending as a percentage of GDP equaled 5.5% in 2002.[82]

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[80] Pan American Health Organization Country Profile (Mexico), at 5-6.

[81] IMS Health World Pharmaceutical Market Summary Issue 12/2003, at 1.

[82] IMS Health Pharmaceutical Market Intelligence, at 1. Accessed February 19, 2004 at http://open.imshealth.com/webshop2/IMSinclude/i_article_200040105.asp. World Health Organization Country Statistics (Mexico), at 1. Accessed February 19, 2004 at http://www.who.int/country/mex/en/.

The Mexican generics market is still in its infancy but is growing rapidly. The generic industry remains controversial because of significant issues concerning its respect for intellectual property protection and questionable quality assurance procedures.

Pricing, Reimbursement and Access:

Mexico has two markets for pharmaceuticals, the private market and the public market. The Government is the largest purchaser of pharmaceuticals in Mexico. Lowest-price criteria are used in determining its pharmaceutical purchases. In the private market, the Department of Standards and Acquisition determines pharmaceutical pricing. Wholesale and retail margins are subject to negotiation between the Government of Mexico and the manufacturer and final retail prices require government approval. As a result of the Government of Mexico's purchasing power, the purchase price of drugs within the government system often becomes the maximum price for the private market.[83]

The pricing system has had a serious impact on the health of Mexican citizens. Because lowest-price criteria are used in purchasing decisions, patients have decreased access to innovative medicines. Seven of the top twenty drugs purchased by the Government of Mexico are over 40 years old. And, in some cases, patients may receive copy products of the therapies that are best suited for their care. These copy products may pose important health risks to the patient, as it is impossible to trace their origin or to state with certainty that they were manufactured in accordance with minimum standards.

In 2003, Government of Mexico proposed the establishment of a reference pricing system for patented medicines. The details of this system are still under review, however, it is clear that OTCs and generics will be exempt from it.

Research and Development:

In the aggregate, the pharmaceutical industry spends on average 5 percent of revenue on research and development in Mexico (nearly exclusively in the form of clinical research done in cooperation with organizations such as medical schools and clinics).

[83] ITC Pricing Study, at 4-36.

THE NETHERLANDS

Health Care Financing:

The Netherlands uses a combination of public sickfunds and private insurance to provide healthcare to its citizens. The Social Health Care Insurance Act (ZFW) and private insurance provides coverage for "curative healthcare". ZFW provides coverage for the majority of the population, 64%. Participation in the ZFW is needs-based and extends to the elderly and beneficiaries of social security. Individuals who do not qualify for participation in ZFW may purchase private insurance.[84]

Supplemental insurance coverage for "exceptional medical expenses" such as long-term care, patients with physical disabilities, mental disorders and National Vaccination Program is available through the Algemene Wet Ziektekosten, AWBZ.

The state is considering reforms targeted at consolidating the health insurance system into a single insurance scheme by 2005.

Pharmaceutical Market:

In 2002, the pharmaceutical market in the Netherlands was valued at € 3,218 million (US$ 3,915 million).[85] Per capita health expenditure totaled € 3,245 (US$ 3,948) in 2002. Total healthcare expenditure as a percentage of GDP equaled 11.8%.

Generic drugs account for a large share of the pharmaceutical market. Approximately 46.3% of prescriptions, although their share in terms of sales is considerably smaller – 19.1% in 2002.

Pricing, Reimbursement, Access:

Pharmaceutical pricing guidelines are promulgated by the Medicines Prices Act, Wet Geneesmiddelenprijzen, WGP. Prices are based on existing pharmacy purchase prices in four reference countries: Germany, Belgium, France and the United Kingdom. The maximum pharmacy purchase price for a pharmaceutical is calculated as the average price of the product in the four reference countries. For calculating a maximum price, a product should be listed in at least two of the four reference countries. Price revisions are conducted on a biannual basis to allow for price changes in the reference countries and exchange rate fluctuations.

The government is considering a proposal to add new reference countries (*e.g.,* southern European countries) in order to reduce prices.

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[84] Pharmaceutical Pricing and Reimbursement 2003 (The Netherlands), at 133.

[85] IMS Health x-trend.

Pharmaceuticals with marketing approval and government-approved prices are eligible for listing in the Drugs Remuneration System. In evaluating whether to reimburse a product, the government considers the product's therapeutic value, associated administrative costs of reimbursement and, from January 1, 2005 onwards, a cost/benefit analysis of the financial benefits of the new product in comparison to older products.

The Netherlands reimburses pharmaceuticals at three categories: Annex 1A, Annex 1B and Annex 2. The majority of pharmaceuticals qualifying for reimbursement fall into the Annex 1A category. Pharmaceuticals within this category are grouped into product clusters and are assigned a maximum reimbursement rate based on the average of products within the cluster. New breakthrough products that are unique from the products in the existing clusters are assigned to the Annex 1B category. For products assigned to Annex 1B and having similar clinical value as products with the same indication already grouped in a product cluster on Annex 1A, the reimbursement limit is the assigned limit in of that cluster on Annex 1A. For products with added clinical value assigned to Annex IB, more flexibility in pricing is permitted, but the budgetary impact of the proposed price has to be acceptable to the Ministry of Health. Additionally, on Annex 2, specific reimbursement requirements can be listed for products already assigned to Annexes 1A and 1B. These additional requirements limit the reimbursement to specified risk or disease groups. For Annex 2 reimbursement, additional requirements are set on a case-by-case basis.[86]

The State is planning to revise ("modernize") the GVS system by January 1, 2005. The proposals that are being considered all focus on a further lowering of the reimbursement limits. The outcome of these proposals will be that in product clusters that contain off-patent products, the reimbursement limit will be heavily influenced by the price of the cheapest generic product in the cluster. Simultaneously, a new price law will reduce the prices of the generics substantially. Eventually, in each cluster only the cheapest generic will be fully reimbursed. It is to be expected that these plans will not only result in substantial co-payments for major products on the market, but also that new product launches of products assigned to Annex 1A can only take place with substantial co-payment. Both the Nefarma and the Pharmaceutical Committee of the Amcham are fighting these plans and have proposed a more reasonable alternative.

Research and Development:

Data not available.

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[86] Pharmaceutical Pricing and Reimbursement 2003 (The Netherlands), at 134-136.

NEW ZEALAND

Health Care Financing:

Universal, public health care is available to all residents; private health insurance is also available for purchase, although it excludes coverage for unsubsidized pharmaceuticals. Access to public health care services and products occurs through a patient's primary health care provider or General Practitioner. New Zealand's stringent cost containment policies appear to be undermining the country's ability to develop a viable local pharmaceutical and biotechnology economy.

Pharmaceutical Market:

In 2002, sales of pharmaceuticals by PhRMA Member Companies totaled NZ $1,018 million (US$ 647 million) in the New Zealand market.[87] Expenditure on subsidized non-hospital pharmaceuticals rose from NZ$503 million (US$ 320 million) in 2002 to NZ$512 million (US$ 325 million) in 2003. In 2002, New Zealand spent 4% of GDP on pharmaceuticals.[88]

Pricing, Reimbursement and Access:

Oversight of pharmaceutical reimbursement in New Zealand is made by PhARMAC, which sits within the Ministry of Health. PhARMAC maintains and administers a Pharmaceutical Schedule of all products that are eligible for reimbursement. To quality for reimbursement, new products are examined on the basis of therapeutic need and cost effectiveness in comparison to older products, as well as overall impact on the health budget. Although cost offsets elsewhere within the health system are considered, no mechanism exists to transfer costs savings achieved back into the capped pharmaceutical budget.

Final approvals for listing on the Pharmaceutical Schedule requires a positive recommendation from PHARMAC's clinical advisors, the Pharmacology and Therapeutics Advisory Committee (PTAC), and a contractual agreement between PHARMAC and the pharmaceutical company on the price and terms of a listing (including patient access criteria). Provisional Agreements are then subject to public consultation with industry representatives, medical professionals, pharmacy groups and patient groups before a final determination as to whether the product will be listed in the reimbursement schedule is made by the PHARMAC Board.[89]

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[87] BCG, "NZ Pharma Industry Review" (Boston, MA.: Boston Consulting Group, 2002): 81.

[88] BCG, "NZ Pharma Industry Review" (Boston, MA.: Boston Consulting Group, 2002):

[89] Braee, Richard, "New Zealand: Pharmaceutical Pricing and Reimbursement Policies" PHARMAC, *available at* http://pharmacos.eudra.org/F3/g10/docs/tse/NewZealand.pdf.

The pharmaceutical industry's major concern is New Zealand is the manner in which PhARMAC exercises monopsonistic power over access to the New Zealand market. PHARMAC regularly conditions its acceptance of a product on reimbursement or the manufacturer's willingness to agree to a generic-level price.

Delays are a major problem plaguing the PHARMAC system. Even where reimbursement has been successfully negotiated with PHARMAC, these delays have averaged 33 months.[90] Numerous products have been delayed for longer periods in the absence of a decision by PHARMAC to list them.

Beyond these delays, PHARMAC's monopsonistic power over the Pharmaceutical Schedule (PS) creates other major barriers to market access by denying or conditioning the listing of new medicines on the willingness of manufacturers to accept discriminatory pricing and reimbursement policies. PHARMAC applies its discriminatory policies in the following manner:

- Grouping together patented products with generics for reference pricing. This policy differs from reference pricing in many other countries and erodes the value of intellectual property accrued through innovation.

- Denying a PS listing when PHARMAC subjectively considers that "sufficient" products are already available to meet patients' needs;

- Denying or conditioning PS listing of new drugs upon the manufacturer's acceptance of a reimbursement level that is less than or equal to the current PHARMAC-imposed reimbursement level of existing medicines (and in many cases, off-patent medicines);

- Denying or conditioning PS listing upon the manufacturers' agreement to set the introductory market price for the private market in New Zealand and at the same level on the PHARMAC reimbursement level, in effect, imposing a maximum price control at the time of listing;

- Denying or conditioning PS listing upon the manufacturer's agreement to Government-mandated cross therapeutic reference pricing which requires a major price reduction on one or more of the company's other medicines, often in a completely unrelated therapeutic class;

- De-listing of medicines based on the award of a single tender or "preferred provider" status; and,

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[90] BCG, "NZ Pharma Industry Review" (Boston, MA,: Boston Consulting Group, 2002).

- Lack of transparency in reference pricing methodology. Clinical evidence and therapeutic differences, as well as the views of physicians are ignored in favor of products with lower reimbursement levels.

Patients are required to pay a co-payment on all reimbursed products. Actual costs are dependent on the patient's age, household income, and the total number of prescriptions used by a family.[91]

Research and Development

No data is available on R&D for New Zealand, although levels are understood to be extremely low.

[91] *Id.*

NORWAY

Health Care Financing:

All Norwegian citizens have universal access to health insurance provided by the National Insurance Scheme (Folketrygden). Financing of the system occurs through general taxation drawn from a special levy placed on all employees. Although the state coordinates financing and oversees the policy direction of the system, management and delivery of primary care services occurs locally at the county and municipal levels.[92] Ownership of hospitals was transferred from the 19 countries to the central government on January 1, 2002, as part of a reform to improve access, quality and efficiency within the hospital sector. Five regional health authorities are responsible for the provision of specialized health services by the hospital trusts. The central government has overall managerial and financial responsibility for the hospital sector, but there is financial freedom within secondary health services.[93]

Pharmaceutical Market:

In 2003, the pharmaceutical market in Norway was valued at 9.6 billion NOK (US$ 64.7 billion). The growth of this market has slowed considerably in recent years. Total healthcare expenditure as a percentage of GNP was 8.0% in 2002.[94]

Pricing, Reimbursement, Access:

The Norwegian Medicines Agency (Statens legemiddelverk, SLV) oversees pharmaceutical pricing and reimbursement. The SLV calculates a maximum pharmacy purchase price for all prescription products based on "an average of the three lowest pharmacy purchase prices" in Finland, Sweden, Denmark, UK, Ireland, Germany, the Netherlands, Belgium and Austria. If prices for three reference countries are not available, the SLV will use the lowest average price in those countries with the product. SLV has introduced a yearly price revision for the 240 highest selling generic substances. Revisions of prices can also occur if the price of a product changes in a reference country or if there is a fluctuation in the exchange rate.

Norway's reimbursement schedule is divided into four categories: automatic reimbursement (listing on the "Blue Prescription List"), individual patient based

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[92] Pharmaceutical Pricing and Reimbursement (Norway), at 143. Furuhlman, C., Magnussun, J. "Health Care Systems in Transition: Norway" (Copenhagen: European Observatory on Health Care Systems, 2000), *available at* http://www.who.dk/document/e68950.pdf .

[93] Pharmaceutical Pricing and Reimbursement (Norway), at 143; Furuhlman, D., Magnussun, J. "Health Care Systems in Transition: Norway."

[94] OECD Health Data 2003, 3rd Ed., Eurostate, EFPIA, LMI.

reimbursement, and reimbursement based on the severity and rarity of the condition treated.[95]

Products that gain listing on the "Blue Prescription List" are typically associated with chronic conditions that require a "minimum of three months' treatment." Short-term treatments are not listed on the Blue Prescription List. Listing of new, innovative products requires approval by both the Ministry of Health and in certain cases the Parliament. As part of the application process for listing, companies are required to submit a pharmacoeconomic evaluation.

Research and Development:

In 2001, research and development expenditures totaled € 94 million (US$ 139 million).[96]

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[95] Pharmaceutical Pricing and Reimbursement (Norway) 2003, at 143-146. Norwegian Association of Pharmaceutical Manufacturers, "Country Report 2003" (Oslo: Norwegian Association of Pharmaceutical Manufacturers, 2003).

[96] EFPIA Pharmaceutical Industry Research and Development in Europe, at 15.

POLAND

Health Care Financing:

As required under Poland's Constitution, public healthcare is available to all residents of Poland. The financing of the Polish healthcare system comes from health insurance contributions through a payroll tax as well as state, regional and local government budgets. Under-funding has been a chronic problem.[97] The system is administered by the Ministry of Health through a National Health Fund that has 16 regional branches.

Pharmaceutical Market:

Poland's pharmaceutical market was valued at US$ 3,593 million in 2003.[98] Health spending per capita totaled US$ 246 in 2000. Total healthcare expenditure as a percentage of GDP equaled 6.0%.[99]

The Polish market is characterized by a strong degree of generic penetration. This is due in part to the lack of effective patent protection until 1993 and discrimination against innovative products in the reimbursement system in recent years. Not a single new innovative product has been added to the government reimbursement list in Poland since December 1998. Largely as a result, generic drugs now account for 65-70% of pharmaceutical consumption by volume and 30% by value.[100]

Pricing, Reimbursement and Access:

The Health Insurance Fund operates a positive reimbursement list. Reimbursement is determined by the Ministry of Health, based upon the recommendations of a Drug Management Team. The members of the Drug Management Team include three representatives from each of the Ministries of Health, Finance, and Economy and may include representatives from the regional branches of the Health Insurance Fund.

Poland operates a reference pricing system for imported pharmaceuticals. Prices established for imported medicines take into account prices in relatively low- priced EU markets, such as France, Greece, Portugal, Spain, the Czech Republic, Hungary, Slovakia and Lithuania.[101] There are no transparent rules upon which price decisions are taken, however, and different reference countries are used for different cases.

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97 Pharmaceutical Pricing and Reimbursement (Poland), at 108.
98 Local pharmaceutical industry estimate.
99 Pharmaceutical Pricing and Reimbursement (Poland), at 107.
100 *Id.* at 158.
101 *Id.* at 153.

A particular problem with the reference pricing system in Poland is its reliance on groupings of products based on the Anatomical Therapeutic Chemical (ATC) / Defined Daily Dose (DDD) system. This system was developed by the World Health Organization (WHO) as an instrument to measure drug consumption. WHO guidelines for use of the system provide that it is "not suitable for comparing drugs for reimbursement and pricing decisions," and that to do so is a "misuse of the system".[102] Nevertheless, the Ministry of Health in Poland uses DDD as a reference dose for establishing the reference price limit in therapeutic clusters and uses the drug with the cheapest DDD as a price limit for reimbursement for other products in the cluster.

Massive delays are one of the most pressing problems with the Polish reimbursement system. A Price Law, implemented in 2001, aimed at ensuring compliance with the EU Transparency Directive, and was supposed to ensure that the decision process did not take longer than 90 days from a price submission or 180 days if both pricing and reimbursement submissions are made simultaneously. The law has been a complete failure. The decision criteria for including new products on the government reimbursement list continue to lack any transparency and the appeal system is inadequate. The legal 180-day period has been exceeded several times over. No new innovative medicines have been added to the reimbursement list for five years, although infringing copies of those medicines actually have been added.

Beyond these bureaucratic manipulations of the pricing and reimbursement regime, Poland has also taken additional extraordinary, budget-driven measures directed at foreign pharmaceutical manufacturers. In an effort to address its budget deficit, Poland changed its customs law in 2003 such that innovative pharmaceutical companies importing medicines were automatically in violation of the new law. Poland immediately then threatened to impose discriminatory fines of $1.5 billion on these importing companies. Domestic companies are not subject to the threatened fine. These massive confiscatory fines are currently pending, and threaten the operations of U.S. pharmaceutical companies operating in Poland.

Research and Development:

R&D of ethical pharmaceuticals by PhRMA Member Companies totaled US$ 71.6 million in 2001.[103]

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[102] WHO, Guide to ATC Classification (2001).

[103] PhRMA Profile 2004: Focus on Innovation, at 42.

PORTUGAL

Health Care System:

Healthcare is provided to all citizens in Portugal through the National Health Insurance scheme. The Portuguese healthcare system covers more than 60% of the population; the system is financed through general taxation. In addition to the National Health Insurance Scheme, there are two other health insurance systems in place: health insurance for specific occupations (subsistemas) and private health insurance. Subsistemas provide full coverage to about 25% of the population. Financing is based on a combination of employer and employee contributions. [104]

Pharmaceutical Market:

The pharmaceutical market was valued at US$ 1, 605 million in 2001. Per capital health expenditure totaled US$ 878. Total healthcare expenditure as a percentage of GDP equaled 8.2%.

Generic drugs account for less than 1% of the market by value in Portugal.[105]

Pricing, Reimbursement, Access:

Pricing is determined by the Directorate-General for Trade and Competition, Direcção-Geral de Comércio e da Concorrência, DGCC, within the Ministry of Economic Affairs. By law, prices are permanently set based on the ex-factory price of identical or similar products in Spain, France and Italy. For pharmaceuticals that are not available in any of the reference countries or only a portion of the reference countries, the Government of Portugal uses several rules to obtain the lowest price possible. Prices are revised on an annual basis.

Generally, generic products are priced by the government at 35% below the level of corresponding innovative products.

Oversight of reimbursement of pharmaceuticals is provided by INFARMED, the National Institute of Pharmacy and Medicines. Products under consideration for reimbursement must be "similar" to existing reimbursed products when compared to safety and efficacy, dosage and therapeutic benefit. Manufacturers are not technically required to conduct pharmacoeconomic studies; however, it is not uncommon for INFARMED to request studies evaluating cost-benefit, cost-minimization, cost-effectiveness and cost-utility of new products.

Generally, reimbursement levels are based on the severity of disease. Category A includes products for chronic conditions such as diabetes and heart disease;

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[104] Pharmaceutical Pricing and Reimbursement (Portugal) 2003, at 161.
[105] *Id.* at 160, 164.

reimbursement is set at 100%. Category B encompasses most medicines with reimbursement set at 70%. Category C includes vaccinations and antibiotics; reimbursement is set at 40%. Finally, Category D is used to reimburse new products "with questionable therapeutic advantages".[106] Patients are responsible for the cost of the products that are not reimbursed.

Research and Development:

U.S. companies spend €5,805,158 in 2002 on R&D in Portugal. More generally beyond the pharmaceutical sector, the Portuguese government's investment on R&D gets a low ranking. Public R&D investment in medical and biological sciences is 60% below the E.U. average.[107]

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[106] *Id.*, at 161-164.

[107] Análise Quantitativa da Indústria Farmacêutica em Portugal, Jorge Vasconcelos e Sá (*Translated : Quantitative Analysis of Pharma)*.

SLOVAK REPUBLIC

Health Care Financing:

Healthcare is provided to all citizens through a system of compulsory health insurance. The Slovak Republic has five insurance programs and citizens are free to choose the system in which they want to participate. The largest insurance programs in the country are the General Health Insurance Company and the Common Health Insurance Company. These two systems are guaranteed by the Government of Slovakia. The remaining insurance systems are privately operated but are required to operate similarly to the state systems.

Financing of all health insurance schemes occurs through a combination of employer and employee contributions, government contributions and out-of-pocket private contributions. Premiums are adjusted according to need; children and retired persons are covered by the state.[108]

Pharmaceutical Market:

The total pharmaceutical market in the Slovak Republic was valued at € 840 million at ex-factory prices in 2003. Innovative pharmaceuticals accounted for approximately 46% of the market value, while generics accounted for approximately 53% of the market value. Total per capita healthcare expenditure equaled US$210 and total healthcare as a percentage of GDP equaled 5.9% (2000 figures).[109]

Pricing, Reimbursement, Access:

The Ministry of Health oversees pharmaceutical pricing and reimbursement in the Slovak Republic. Prices are based on two sets on criteria depending on whether the product is imported or produced locally. A maximum price is set for imported products based on a comparison of existing prices from a basket of nine European countries including the Czech Republic, Poland, France, Austria, Hungary, Spain, Italy and Germany. In contrast, the maximum price of locally produced products is based on production costs. Price revisions occur on an annual basis and are subject to application. Generally, price revisions are granted when there is an increase in the cost of production of more than 5%, or a change in the exchange rate. Recent legislation offers importers the same cost-based pricing available to domestically produced products, but implementation of this legislation is uncertain.

Reimbursement decisions are also made by the Ministry of Health. Several factors including a drug's safety and efficacy, dosage, strength, administrative

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[108] Pharmaceutical Pricing and Reimbursement (Slovak Republic) 2004, at 129.

[109] *Id.*, at 128. Slovak Republic Pharmaceutical Industry statistics.

cost and therapeutic value in comparison to existing products are used to determine whether a product qualifies for inclusion.

The government reimburses pharmaceuticals at three rates: full reimbursement, partial reimbursement and no reimbursement. Products gain classification into each rate based on a comparison to existing products of similar therapeutic value. Generally, only the cheapest generic product in a class gains full reimbursement status.

In June 2003 the Government of Slovakia adopted new rules governing the price of reimbursed products. Under the new rules, the Ministry of Health encourages insurance companies to implement prescribing budgets with contracted doctors.[110]

Research and Development:

No data on R&D levels in the Slovak Republic is available.

[110] Pharmaceutical Pricing and Reimbursement (Slovak Republic) 2004, at 129-133.

SPAIN

Health Care Financing:

Spain's National Health Service provides near universal coverage to its citizens. Health care is administered through Spain's 17 regions (autonomous communities), and is financed through general taxation and social security contributions. Oversight is provided by the Ministry of Health and Consumer Affairs. [111]

Pharmaceutical Market:

Spain's pharmaceutical market was valued at US$ 7,742.9 million in 2003. U.S. pharmaceutical firms represent 28% of the market. [112]

Healthcare spending per capita in Spain totals approximately US$ 955. [113] Total healthcare expenditure as a percentage of GDP equals 7.5 %.[114] Public healthcare spending as a percentage of total health care spending equaled approximately 70%, and public spending on pharmaceuticals as a percentage of total healthcare spending equaled approximately 21.1% in 2003.[115]

Generic penetration of the pharmaceutical market is not extensive due to the alignment of branded and generic products at the low reference prices. Generic market share in 2003 was 5.8 % by volume and 4.2% by value.[116] The government's long-term goal, however, is for generics to comprise approximately 10-15% of the overall market share.

Pricing, Reimbursement and Access:

Like most other European countries, Spain maintains a positive list of products approved for reimbursement. Strict price controls apply to reimbursed products.

A new administrative procedure was issued on December 2002 for the coordination of the reimbursement and the pricing process, and companies seeking reimbursement for their products must go through both procedures and thereafter comply with certain paperwork and formalities in order to market a reimbursed medicine. Due to this new reimbursement-pricing process, access to the Spanish market is commonly delayed substantially longer than the maximum timing (180 days) permitted under the European Transparency Directive.

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111 Rico, A., Sabes, R., Wisbaum, W. "Health Care Systems in Transition: Spain."
112 IMS Health, S.A.
113 Spanish Ministry of Health.
114 Spanish National Institute of Statistics.
115 Spanish Ministry of Health.
116 IMS Health, S.A.

Generally 60% of the cost of a drug is reimbursed. Drugs for chronic therapies (such as depression, schizophrenia or diabetes) are 90% reimbursed. Hospitalized patients have 100% drug coverage. Retired patients also have 100% reimbursement regardless of the drug class or delivery setting.

Prices of reimbursable prescription drugs are determined by a pricing commission (Comisión Interministerial de Precios de los Medicamentos) which operates under the ministry responsible for health. Manufacturers are required to submit to the Commission a pricing dossier containing financial records, expected level of sales and profit, prices of similar drugs in Spain and in other countries, and evidence of the drug's therapeutic advantages.

Under Spain's reference pricing systems, the maximum reimbursed price of any drug is set at the simple average price of the three cheapest products in a therapeutic group. Moreover, if a physician prescribes a branded drug that is priced above the reference price, a pharmacist must instead give the patient the cheapest generic product available.

In the past, Spain has also relied on mandatory rebates as a means of reducing the effective price to the government of pharmaceuticals. Often government price approvals require the acceptance by the innovator company of sales caps and individual pay-back agreements if the cap is exceeded. In addition, at the industry level, since October 2002, pharmaceutical manufacturers have been obligated to pay back a minimum of €150 million (US$ 180 million) over three years, regardless of the government's level of pharmaceutical expenditure.[117]

Prescribing and dispensing controls are also applied to innovative high volume products at both the national and regional levels in Spain. One of the more drastic cost-containment measures is the so called "visado" limitation, which consists mainly in conditioning the dispensing of certain products on an administrative burden of stamping each prescription by an inspector, before the patient is able to obtain the reimbursed drug at the pharmacy. Several regions have established budgets for primary care physicians and penalize those doctors for so-called "excess" prescribing.

Finally, parallel trade continues to be a major problem in the Spanish market due to significant price differentials in the artificial governmental determined prices in Spain compared with other major European markets. Speculative wholesalers regularly take advantage of the government's policies to export large quantities of Spanish price-controlled drugs to markets where the government price controls are more flexible.

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[117] *Id.*, at 173.

Research and Development:

In 2002, pharmaceutical R&D in Spain was US$ 125 million.[118]

[118] PhRMA Profile 2004: Focus on Innovation, at 42.

SWEDEN

Health Care Financing:

Sweden provides universal healthcare including pharmaceutical reimbursement to all citizens. The system is decentralized with management and delivery of services occurring at the county level. Each county operates autonomously and provides services according to the needs of its population. Financing of primary care and hospitals occurs through regional taxation, whereas pharmaceuticals are funded through a national payroll tax. These revenues are allocated annually to each county based on need. Unused revenues may be carried over to the next year.

For reimbursed pharmaceuticals, the State provides each county with an annual grant. Counties have to cover any expenditures above the level of the grant.

Pharmaceutical Market:

The pharmaceutical market in Sweden was valued at US$ 3,101 million in 2003. Total per capita healthcare expenditure in 2002 equaled US$ 2,734. Total healthcare expenditure as a percentage of GDP equaled 8.0%.

In 2003, generic drugs accounted for 13.27% of the value of the pharmaceutical market. When a patient presents a prescription for a branded drug to a pharmacist, the pharmacist is require to substitute a generic prescription unless it is expressly prohibited by the doctor on the prescription, or unless the patient refuses such substitution and pays the difference in cost.

Pricing, Reimbursement and Access:

The Pharmaceutical Benefits Board (Läkemedelsförmånsnämnden, LFN) determines pricing and reimbursement of pharmaceutical products in Sweden. The LFN bases pricing decisions on criteria such as therapeutic and socioeconomic value. Generally, prices are referenced to the average price of a group of products with similar therapeutic value. Technically, products with demonstrable therapeutic value are eligible for a higher price. These price controls do not apply to generic drugs. Generic products are priced freely so long as the price is below the most expensive comparable product.

There is a system for co-payment in the Swedish reimbursement system not tied to a specific product but depending on the total consumption of pharmaceuticals during a 12 month period. Patients are responsible for different percentage shares of the cost of all drugs up to a fixed annual amount. The cost of drugs above this threshold amount is subsidized entirely by the Government for the remainder of the year. Patient co-payments add up to approximately 20% of the total bill for reimbursed medicines (excluding hospital sales).

In principle, coverage decisions made at the national level by LFN should be followed by the county councils. However, the local and regional formulary committees, with a long tradition of recommending drugs of choice, increasingly issue recommendations of a different kind. Due to the stringent cost-containment programs in place, in most county-councils the "recommendations" have direct impact on prescription patterns. These local practices, pursuant to which health care providers do not follow central policy decisions (LFN), is the greatest access problem in Sweden at the present time.

Research and Development:

In 2001, pharmaceutical research and development expenditures totaled US$1,648 million. Total R&D expenditure across all industries in Sweden amounts to 4% of GDP, of which 75% represents private investments.

SWITZERLAND

Health Care Financing:

Health insurance is mandatory for all citizens in Switzerland. The legal basis is a federal law on sickness insurance (Krankenversicherungsgesetz, KVG). Management, delivery and financing of health services occur locally at the canton level. Each canton operates differently in response to the population's needs and size and within the given frame of the KVG. Financing of the system occurs through mandatory private insurance (65% of all funds) as well as government contributions, general taxation collected locally, and patient co-payments.

Pharmaceutical Market:

In 2003, the pharmaceutical market was valued at CHF 3877 million or US$ 2,982 million. The market growth was 7.1%, slightly below the estimated growth of the world market of 8%.

Total per capita healthcare expenditure equaled US$ 3, 841, an increase of 4% over the previous year. Total healthcare spending as a percentage of GDP equaled 11.2%.

In 2003, generic drugs accounted for 3.6% of the value of the pharmaceutical market. This represents an increase of 0.6% over the previous year attributable to the fact that some major products went off patent and a new generic law went into effect.

Pricing, Reimbursement, Access:

The Swiss Federal Office of Public Health (Bundesamt für Gesundheit, BAG) makes decisions concerning pricing and reimbursement of pharmaceuticals. BAG bases the maximum price for reimbursed pharmaceuticals on two criteria: First, BAG calculates the average price of the product in a group of reference countries (Germany, the UK, Denmark and the Netherlands). Second, BAG evaluates the new product's therapeutic and economic value in comparison to older products of the same therapeutic group. If either criterion can not be applied, BAG will consider the manufacturer's suggested price as the maximum price. Generic products are subject to a similar procedure. Since January 2004, new generics must be priced 30% below the price of the branded products. Price revisions are conducted two years after reimbursement has been granted, and after a patent has expired or after 15 years of reimbursement. Sales volume and price comparisons are factors that influence revisions in price.

The Swiss Agency for Therapeutic Products (Swissmedic) categorizes all pharmaceuticals into five lists (list A - E). Listing decisions are based on the pharmacological effects of the active ingredient, acute and chronic toxicity,

clinical experience, therapeutic indications(s), potential for misuse, and need to have a medical examination before starting the treatment. Usually, pharmaceuticals that are reimbursed are found on List A, List B or List C. Drugs appearing on the list of reimbursed products (Spezialitätenliste, SL) are those that are available on a prescription basis or those non-prescription products that are only available in pharmacies (List C).

Patients in Switzerland are required to pay an annual premium to their insurer towards the cost of pharmaceuticals. Co-payment is 10% of the public price of the pharmaceutical up to a given maximum, depending on the insurance model the patient has chosen.

Research and Development:

In 2002, Swiss pharmaceutical companies invested approximately CHF 3 billion (US$ 2.3 billion) into R&D. Foreign headquartered pharmaceutical companies spent approximately CHF 280 Million (US$ 215 million).

TURKEY

Health Care Financing:

There is no universal health coverage in Turkey. About 83 percent of the population has healthcare coverage under five main state-run insurance schemes.[119] These are: (1) the Social Insurance Organization (SSK) for manual labor workers, (2) the Government Employment Retirement Fund (Emekli Sandigi) for retired civil servants, (3) the Social Insurance Agency for Merchants, Artisans, and the Self-employed (Bag-Kur), (4) active government employees and their dependents have comprehensive healthcare coverage as a part of their employment contract, and (5) the Green Card Scheme for indigents. Financing of these schemes occurs through a mixture of government contributions and employer/employee contributions, except for the last two which are entirely financed by the government.

Due to an increasing budget deficit of the insurance scheme, the Government of Turkey has adopted severe cost-containment policies targeting pharmaceutical expenditures and investment in hospitals and diagnostic centers in recent years.[120]

Pharmaceutical Market:

In 2003, the total outpatient pharmaceutical market was valued at US$ 3,486 million (IMS). Total per capita healthcare spending in 2002 equaled US$ 150 and total spending of healthcare as a percentage of GDP equaled 5.0%.

Pricing, Reimbursement, Access:

Historically, prices of prescription drugs have been subject to price controls and reimbursement of drugs was subject to a positive listing scheme in Turkey. These policies became substantially more stringent in 2002 when the government introduced reference pricing first in Bag-Kur. The reference pricing scheme was extended to Emekli Sandigi in March 2003. At present, the government is considering expanding the reference pricing policy to other social insurance schemes as well.

In February 2004, the Government imposed further modifications, changing to a stringent and inflexible form of international reference pricing. All pharmaceutical prices are now to be referenced to the lowest price found within five predetermined European Union countries (currently Italy, Spain, Greece, France and Portugal). Upward adjustments are not be allowed.

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[119] Health Care Systems in Transition, Turkey, 2002.

[120] Pharmaceutical Pricing and Reimbursement (Turkey) 2003, at 151.

The Government has also recently begun to impose greater prescription restrictions through the so-called Budget Implementation Guidelines.

Research and Development:

Although there is no official data on R&D spending in Turkey, it is estimated that research based pharmaceutical companies spend approximately USD $15-20 million in Turkey, mainly in clinical research activities.

UNITED KINGDOM

Health Care Financing:

Public health care is available to all residents through the government-managed National Health Service (NHS). The NHS is funded primarily through general taxation, but also derives funds from national insurance contributions and patient co-payments. Private insurance schemes are available, and usually provide supplementary coverage.

Pharmaceutical Market:

The UK pharmaceutical market was valued at £ 8,600 million (US$ 15,440 million) in 2002. NHS healthcare expenditures accounted for approximately 12.6% of the market. The NHS encourages generic prescribing and 78% of scripts are written generically. This means when a product goes off patent, there is rapid generic erosion. In 2003, the generic market grew at 39% in the UK versus 5% in the branded sector.

Pricing, Reimbursement and Access:

The UK relies on a system of profit controls for pharmaceuticals. Thus manufacturers are free to determine the initial price of a product. All prescription-only medicines are reimbursed by the NHS, unless they are on the "Selected List Scheme" (SLS), a negative list which includes 2000 products in 17 categories. For those products reimbursed by the NHS, pricing is subject to the Pharmaceutical Price Regulation System (PPRS), and any increase must be authorized by the Department of Health (DOH). For prescription only medicines, patients face a co-payment of £6.40 for each item dispensed. Nevertheless, few actually pay the co-payment as most of the population qualifies for exemptions.

The PPRS' profit framework is fixed for each individual manufacturer based on their level of investment in the UK. If profits exceed the target level, excess profits must be repaid to the NHS, or prices will be lowered for the next period. The government also uses the PPRS system as a mechanism to impose occasional across-the-board price cuts. The PPRS' profit control scheme dampens innovation and efficiency by introducing non-market considerations into investment decisions

The National Institute for Clinical Excellence (NICE) develops guidelines on clinical and cost-effectiveness of new treatments for the guidance of health care professionals. Following a NICE appraisal, products are categorized as recommended for routine use in NHS, recommended only for use in the clinical trials to help answer specific questions about cost-effectiveness, or not recommended for use. The establishment of 'NICE' appraisals has introduced another barrier to entry in the UK. Funding is prioritized to those products

appraised by NICE. Where a new product enters the market in a therapeutic class which has already been evaluated, it may be several years before that product is appraised which puts it at a significant disadvantage versus appraised competitor products.

Under the NICE guidelines, patient choice and clinical freedom are limited. Access to innovative therapies may be restricted or denied. In some cases it is not possible for the doctor to provide the best possible care to an individual patient, since doctors are not able to interpret NICE guidelines in the context of the particular circumstances of each individual patient.

Research and Development:

Aggregate industry research expenditures totaled £ 3,172 million. Pharmaceutical R&D has been relatively flat in the last three years.